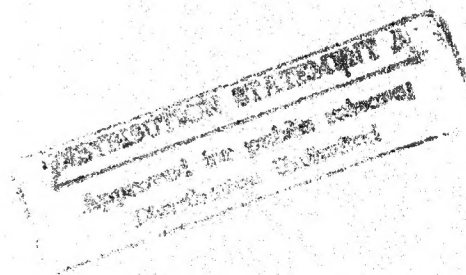
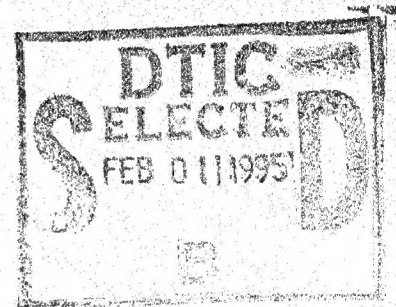


August 1990

DISINFECTANTS

EPA Lacks Assurance They Work

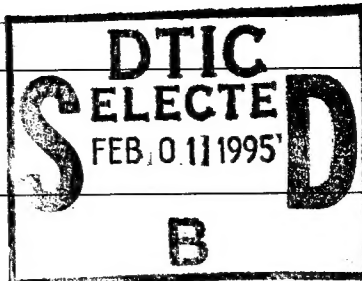


19950127 034

DTIC QUALITY INSPECTED 3



United States
General Accounting Office
Washington, D.C. 20548



Resources, Community, and
Economic Development Division

B-236877

August 30, 1990

The Honorable John Conyers, Jr., Chairman
The Honorable Frank Horton, Ranking Minority Member
Committee on Government Operations
House of Representatives

The Honorable Mike Synar, Chairman
The Honorable William F. Clinger, Jr., Ranking Minority
Member
Environment, Energy and Natural Resources Subcommittee,
Committee on Government Operations
House of Representatives

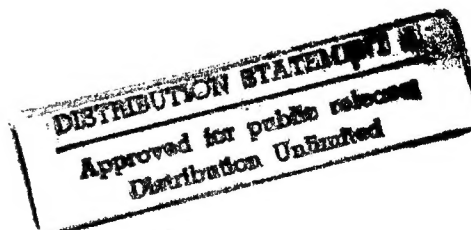
Accession For	
NTIS GRA&I	<input checked="" type="checkbox"/>
DTIC TAB	<input type="checkbox"/>
Unannounced	<input type="checkbox"/>
Justification	
By	
Distribution	
Availability Codes	
Dist	Avail and/or Special
A-1	

This report responds to your request that we review the Environmental Protection Agency's (EPA) activities to regulate the efficacy of disinfectants. Specifically, it describes the nature of the scientific controversies surrounding EPA-recommended methods and performance standards for testing the efficacy of disinfectants, efforts EPA has made to obtain objective research to resolve these controversies, the adequacy of EPA's internal controls to ensure the quality and integrity of registrant-submitted efficacy data, post-registration efforts EPA and the states have implemented to ensure that disinfectants on the market are effective, and the need and options for a laboratory to research and test the efficacy of disinfectants.

Unless you publicly release its contents earlier, we will make no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies of the report to appropriate congressional committees; the Administrator, EPA; and other interested parties.

This report was prepared under the direction of Richard L. Hembra, Director, Environmental Protection Issues, whom you may contact at (202) 275-6111 if you or your staff have any questions. Other major contributors are listed in appendix II.


J. Dexter Peach
Assistant Comptroller General



Executive Summary

Purpose

Disinfectants—about a \$1 billion per year market—are used to kill germs on inanimate surfaces and objects in hospitals, schools, restaurants, and homes. Because users cannot see whether disinfectants kill bacteria, fungi, and viruses, the use of ineffective disinfectants poses a threat to public health and wastes consumer dollars.

Mounting concerns about whether hospital and household disinfectants work as claimed and the adequacy of the Environmental Protection Agency's (EPA) disinfectants program led the House Committee on Government Operations to request that GAO review EPA's regulation of the efficacy of disinfectants.

Background

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA generally must register (license) pesticide products, including disinfectants, before they are marketed. EPA may register a pesticide product only if EPA determines that it is effective, when used as claimed, without causing an unreasonable risk to health or the environment. For most pesticides, EPA allows the marketplace to regulate product performance (efficacy) because users can see whether the pesticide is effective against the target pest. However, registrants of disinfectants intended to protect public health must submit efficacy data to substantiate each product performance claim and use.

Until 1982, EPA conducted limited preregistration confirmatory and post-registration enforcement tests on disinfectants at its laboratory facilities in Beltsville, Maryland. EPA discontinued disinfectant testing in 1982 primarily because of budget constraints. Currently, EPA relies on its review of registrant-submitted efficacy data to register disinfectants. As of September 1, 1989, about 4,100 disinfectants for public-health use were registered with EPA, representing about 18 percent of approximately 23,000 registered pesticide products.

Results in Brief

EPA does not know whether disinfectants kill the germs claimed on product labels for four reasons. First, although the validity of methods and performance standards used to assess the efficacy of disinfectants has been the source of scientific controversy for over a decade, EPA does not independently test disinfectants before registering them and lacks criteria to assess the validity of registrant-proposed test methods and modifications. Second, EPA has made little progress in resolving these controversies because of budget constraints and inadequate research management. Third, EPA lacks sufficient internal controls to ensure the

quality and integrity of the data that registrants submit on disinfectant efficacy. Fourth, EPA lacks an enforcement strategy to ensure that, once registered, disinfectants sold and distributed in the marketplace work as claimed.

The extent to which ineffective disinfectants are marketed is unknown. Although the scientific controversies cloud the issue somewhat, evidence from EPA, the states, and others suggests that up to 20 percent of disinfectants on the market may be ineffective.

Principal Findings

Validity of Test Methods

EPA lacks assurance that the test methods and performance standards used by registrants to substantiate disinfectant efficacy claims are valid. EPA primarily relies on standard-setting organizations, such as the Association of Official Analytical Chemists (AOAC) and the industry itself to develop test methods and performance standards. However, these methods and standards have been embroiled in scientific controversies for over a decade. For example, scientists have debated whether the AOAC Use-Dilution Method, the most widely used test method, is reproducible, accurate, and precise, and whether the performance standard (pass/fail criterion) established by EPA is valid. Although EPA believes that the existing methods and standards are acceptable for registering and enforcing disinfectant efficacy claims, the controversies have impaired the credibility of the disinfectant program. An ad hoc industry/state group recently has developed a test method to replace the AOAC Use-Dilution Method and is expected to present the results of its research to the AOAC in September 1990. EPA officials believe that the new method is reproducible and reliable and will consider whether to require that disinfectants be retested using it after AOAC considers it for adoption.

EPA has contributed to the controversies by accepting test methods and modifications without criteria and independent laboratory data for evaluating their validity. For example, EPA accepts three different test methods to demonstrate that disinfectants kill tuberculosis bacteria. At least one product tested under two of the methods produced substantially different results. Although EPA has registered the product on the basis of one of the methods, EPA lacks the laboratory information needed to explain the differences in results between the methods.

Although EPA has been aware of the scientific controversies for years, it has made little progress in resolving them because of problems in conducting needed research. EPA's 6-year, \$384,000, cooperative agreements with the University of North Carolina did not fulfill EPA's research objectives to improve disinfectant efficacy methods because EPA inadequately managed the agreements. EPA has also made little progress in conducting additional research because of budget constraints. In April 1990, EPA announced that it would spend \$600,000 for research on certain disinfectant efficacy methods and estimated an additional \$1.2 million will be needed.

Controls Over Quality and Integrity of Data

To ensure the quality and integrity of registrant-submitted disinfectant data, EPA reviews the data prior to registration and performs laboratory inspections and data audits. GAO, however, found internal control weaknesses in these programs. For example, EPA has not inspected the majority of labs that have performed disinfectant efficacy studies. In fact, EPA was aware of only 12 of the 92 labs that had performed these studies. Although these programs need to be improved they, in themselves, are not an adequate substitute for a preregistration program to selectively test disinfectant efficacy by an independent laboratory. Data reviewers, lab inspectors, and data auditors generally cannot identify cases in which registrants have selectively submitted data indicating that their disinfectants work because they generally do not observe the tests in progress and no physical evidence remains from the tests conducted.

Monitoring and Enforcement of Marketed Disinfectants

EPA's registration process by itself cannot provide assurance that disinfectants are effective because registrants could market ineffective batches, either intentionally or inadvertently, after registering them. However, EPA does not enforce the efficacy claims of disinfectants on the market. EPA discontinued its limited enforcement testing program in 1982 primarily because of budget constraints. Since 1982, EPA has looked to the states, user groups, and the industry to enforce efficacy claims. However, GAO found few states and no users monitoring disinfectant efficacy because of cost concerns. Only five states test disinfectants for efficacy, and these states have limited programs. Moreover, EPA lacks a strategy to channel complaints about potentially ineffective disinfectants from the states, user groups, and the industry and to take appropriate enforcement action against disinfectants found to be ineffective. Although EPA needs to resolve the scientific controversies that surround disinfectant efficacy test methods and performance standards,

these controversies should not prevent EPA from developing an enforcement strategy, in conjunction with the states, user groups and industry, to ensure that marketed disinfectants work as claimed. Public health and consumer welfare may be compromised without such assurance.

Recommendations

GAO is making recommendations to the Administrator, EPA, to correct deficiencies and restore credibility in the disinfectant program, including (1) developing a plan to resolve the scientific controversies that surround disinfectant efficacy test methods and performance standards; (2) developing and publishing a policy that establishes criteria for evaluating the validity of new test methods and modifications, including criteria for determining when independent laboratory data are needed for validation; (3) improving internal controls over its current programs to ensure the quality and integrity of registrant-submitted efficacy data and conducting preregistration tests to selectively verify registrant claims; (4) establishing an enforcement strategy in conjunction with the states, user groups, and industry to ensure that marketed disinfectants work as claimed; and (5) preparing a cost-benefit analysis of alternatives for a laboratory facility to research and test the efficacy of disinfectants, including the option of charging fees to register disinfectants to help finance such a facility.

Agency Comments

GAO did not obtain official agency comments on this report. GAO did, however, discuss the factual content of the report with EPA officials and has included their comments where appropriate. EPA officials generally agreed with the accuracy of the facts but believed that, as presented, the report could be misread and suggested changes for presenting the facts. GAO made some revisions to the report on the basis of EPA's comments. GAO believes that the report is a fair and accurate presentation of the issues.

Contents

Executive Summary		2
<hr/>		
Chapter 1		8
Introduction		
	Federal Regulation of Disinfectants	8
	Disinfectant Types and Uses	9
	Overview of Efficacy Data Requirements	12
	Disinfectants and Infection Control	14
	Prior GAO Reports	16
	Objectives, Scope, and Methodology	16
<hr/>		
Chapter 2		20
EPA Lacks Assurance	Scientific Controversy Over Methods and Standards	20
That Efficacy Test	Methods Acceptance Process Inadequate	24
Methods Are Valid	Limited Progress Made in Resolving Controversies	28
	Conclusions	34
	Recommendations	35
<hr/>		
Chapter 3		37
Controls Over Quality/	Weaknesses Impair Data and Lab Reviews	37
Integrity of Efficacy	Preregistration Testing Needed to Ensure Data Integrity	41
Data Questionable	Internal Controls Inadequate	44
	Conclusions	44
	Recommendations	45
<hr/>		
Chapter 4		47
Limited Monitoring/	Federal Enforcement Testing Discontinued	47
Enforcement of	Nonfederal Testing Limited	48
Registered	Some Marketed Disinfectants May Be Ineffective	53
Disinfectants	Conclusions	55
	Recommendations	55
<hr/>		
Chapter 5		57
Alternatives for a	Need for and Objectives of a Disinfectant Laboratory	57
Disinfectant	Suggested Criteria for Evaluating Alternatives	58
Laboratory	Alternatives for a Laboratory Facility	59
	Fees for a Disinfectant Laboratory	61
	Conclusions	61
	Recommendations	62

Appendixes	Appendix I: Affiliations of Individuals GAO Contacted	64
	Appendix II: Major Contributors to This Report	66
Glossary		67
Tables	Table 1.1: Selected Disinfectant Efficacy Claims	10
	Table 1.2: Estimated Average Annual Amount of Disinfectants Sold in the United States, 1985-87	12
	Table 1.3: EPA-Recommended Methods for Testing Disinfectants Intended for Use on Hard Surfaces	13
Figures	Figure 1.1: Registered Disinfectant Efficacy Claims by Type	11
	Figure 4.1: Disinfectant Enforcement Samples Tested by North Carolina, Florida, and Mississippi, 1983-89	50

Abbreviations

ADA	American Dental Association
AOAC	Association of Official Analytical Chemists
CDC	Centers for Disease Control
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FMFIA	Federal Managers' Financial Integrity Act of 1982
GAO	General Accounting Office
GLP	good laboratory practice
LDIAD	Laboratory Data Integrity Assurance Division
NSF	National Sanitation Foundation
OCM	Office of Compliance Monitoring
OPP	Office of Pesticide Programs
OPTS	Office of Pesticides and Toxic Substances
PDMS	Pesticide Document Management System
PPIS	Pesticide Product Information System
TSCA	Toxic Substances Control Act
UNC	University of North Carolina

Introduction

Disinfectants¹ are used almost everywhere people want to kill disease-causing microorganisms—in households, hospitals, schools, restaurants, day care centers, dairy farms, and a host of other places. About \$1 billion a year is spent on disinfectants to kill bacteria, fungi, and viruses in bathrooms, kitchens, and offices; on medical and dental instruments, diaper pails, and eating utensils; and at many other locations. Although the role of the inanimate environment in transmitting infections has not been completely defined, the use of disinfectants is considered an important part of infection control programs. In fact, health-care organizations recommend, and many public health ordinances require, their use.

Federal Regulation of Disinfectants

The Environmental Protection Agency (EPA) regulates disinfectants as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA).² Under FIFRA, disinfectants generally must be registered (licensed) by EPA before they may be sold, held for sale, or distributed in commerce. EPA may register a disinfectant only if EPA determines that it is effective, when used as directed, without causing an unreasonable risk to public health or the environment. EPA requires disinfectant firms to submit, among other things, data demonstrating that their products are effective as claimed before EPA will register them. As of September 1, 1989, about 4,100 disinfectants were registered with EPA. These disinfectants represented about 18 percent of approximately 23,000 registered pesticide products.

As permitted under FIFRA, EPA has waived all requirements for pesticide firms to submit efficacy data except for (1) disinfectants and (2) pesticides that claim to control vertebrates that may transmit diseases to humans, such as rodents, birds, and skunks. EPA retains the requirement for disinfectants because users cannot see whether disinfectants kill microorganisms that may cause human disease, such as the bacteria that cause food poisoning, and because the use of an ineffective disinfectant

¹As defined by EPA, “disinfectant” refers to only one of several types of antimicrobial pesticides, which, with some exceptions, are substances intended to inhibit or destroy microorganisms (bacteria, fungi, viruses, and spores). However, we use the term “disinfectant” in this report to broadly describe all antimicrobial pesticides intended to protect public health. For explanations of specific disinfectant efficacy claims, see table 1.1 and the glossary.

²Disinfectants, which are used on inanimate surfaces, are distinct from antiseptics, which are used on skin and other living tissue. Antiseptics are regulated by the Food and Drug Administration. Disinfectants that are used in or on medical devices, such as dialysis machines, are regulated by both EPA and the Food and Drug Administration.

poses a threat to public health. By contrast, EPA does not require registrants to submit efficacy data for other pesticides because users generally can tell whether they work, and the marketplace can regulate product performance. In addition, registrants of pesticides that target microorganisms that do not cause diseases in humans, such as those that target slime-forming or odor-causing bacteria, are not required to submit efficacy data. EPA does, however, require all registrants to be able to show that their products are effective on demand for such data.

EPA's Office of Pesticides and Toxic Substances (OPTS) is responsible for regulating pesticides, including disinfectants. Within OPTS, the Office of Pesticide Programs (OPP) and the Office of Compliance Monitoring (OCM) are responsible for evaluating pesticides for registration and for planning and coordinating pesticide compliance/enforcement activities, respectively. The Antimicrobial Program Branch (formerly the Disinfectants Branch), within OPP, is responsible for registering disinfectants. Within the branch, the Efficacy Evaluation and Technical Management Section is responsible for approving and recommending methods for testing the efficacy of disinfectants and evaluating registrant-submitted efficacy data.

Disinfectant Types and Uses

EPA registers disinfectants with a variety of efficacy claims for use in many areas of the inanimate environment. Disinfectant types and uses range from products intended to kill bacteria on hard surfaces in bathrooms to products intended to chemically sterilize medical instruments in hospitals.

A disinfectant may claim one or more of a number of types of efficacy. The types of efficacy claims a disinfectant may make depend on, among other things, the types of microorganisms the disinfectant targets (e.g., tuberculosis or a polio virus) and the disinfectant's intended level of activity (e.g., a reduction in the level of the microorganism or a complete kill). (For a list of selected disinfectant efficacy claims, see table 1.1.)

Table 1.1: Selected Disinfectant Efficacy Claims

Sterilizer	The disinfectant, sometimes called a sporicide, is intended to destroy or eliminate viruses and all living bacteria, fungi, and their spores. (The claim denotes killing all microorganisms, including the highly resistant spore forms, and indicates that the disinfectant will produce the highest level of disinfection possible.)
Tuberculocide	The disinfectant is intended to destroy or inactivate tuberculosis bacteria. (Tuberculocidal claims are often used by medical users of disinfectants as an indicator of product strength because tuberculosis bacteria are more difficult to kill than most other species of bacteria.)
Disinfectant	The disinfectant is intended to destroy or inactivate one or more major species of bacteria, depending upon whether the disinfectant makes a "limited," "general," or "hospital" disinfectant claim.
Fungicide	The disinfectant is intended to destroy fungi.
Virucide	The disinfectant is intended to destroy or inactivate one or more specific viruses named on the disinfectant's label.
Sanitizer	The disinfectant is intended to reduce the number of living bacteria or viable virus particles.

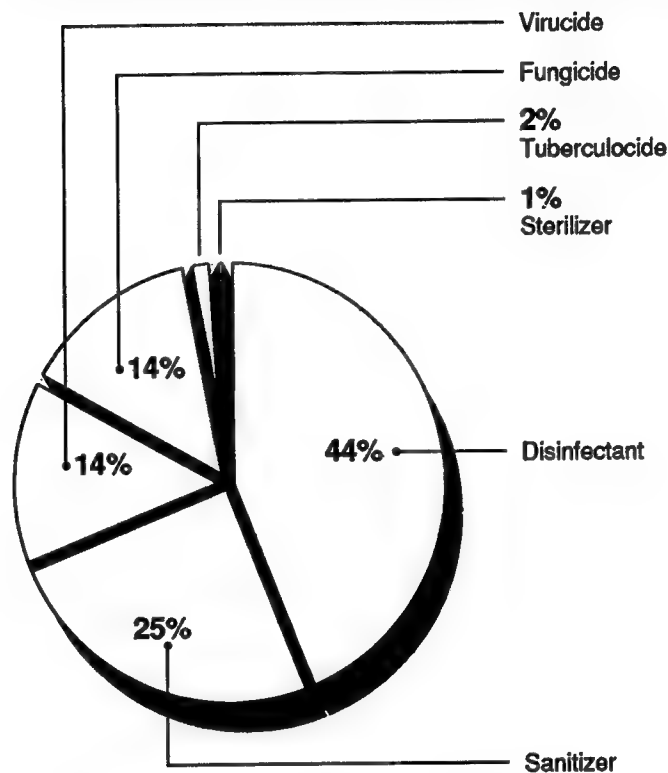
Source: Prepared by GAO on the basis of EPA disinfectant efficacy data requirements and the definition of disinfectant from footnote 1.

We used EPA's Pesticide Product Information System (PPIS) to obtain EPA's best available data on registered disinfectant claims. According to the system, about 4,100 disinfectants³ were registered with EPA as of September 1, 1989.⁴ These disinfectants made about 8,000 different efficacy claims or, on average, about 2 claims per disinfectant. The most common efficacy claim was "disinfectant." (See fig. 1.1.)

³EPA registers both end-use products (products for sale at the retail level) and manufacturing-use products (active ingredients for use in end-use products). Because EPA requires a complete efficacy profile only on end-use products, we did not include manufacturing-use products in our counts of disinfectants.

⁴The 1988 amendments to FIFRA imposed user fees on pesticide registrants to help fund an accelerated review of older pesticides and expedited registration of new pesticides. In 1989, EPA canceled over 6,000 disinfectant registrations because registrants decided to abandon their registrations rather than pay the required fees.

Figure 1.1: Registered Disinfectant Efficacy Claims by Type



Data are for end-use products as of September 1, 1989.

Water purifier claims were not included because they represented less than 1 percent of all registered disinfectant efficacy claims as of September 1, 1989.

Source: Prepared by GAO on the basis of data from the EPA Pesticide Product Information System.

In addition to the types of efficacy claimed (e.g., tuberculocidal), each registered disinfectant must specify the use patterns for which the disinfectant is recommended. Broad categories of use patterns include the use of a disinfectant (1) to kill microorganisms on hard surfaces, (2) to kill microorganisms on fabrics or textiles, (3) to control microbial pests associated with human or animal wastes, and (4) to treat water systems. Registrants typically label their disinfectants for use at specific sites within these broad categories. For example, a disinfectant intended for use on hard surfaces may be labeled for use on counter tops, medical instruments, floors, or other types of hard surfaces.

According to PPIS, as of September 1, 1989, the approximately 4,100 disinfectants made about 18,100 specific use site claims. About 76 percent

of the disinfectants, or 3,200, were registered for use on at least 1 hard surface site. Some of the common hard surfaces for which disinfectants were registered were the surfaces in bathrooms, hospitals, and eating establishments, and at commercial/industrial sites.

EPA has limited data on the size of the disinfectant market. However, data from a private market research firm indicates that the disinfectant market is about \$1 billion per year at the retail level in the United States. In addition, as table 1.2 illustrates, the estimated average annual amount of disinfectants sold represented a substantial amount of all pesticides sold in the United States during 1985-87.

Table 1.2: Estimated Average Annual Amount of Disinfectants Sold in the United States, 1985-87

	Pounds and gallons in thousands			
	Amount sold		Percentage of	
	Dry or solid chemical product (lbs.)	dry or solid chemical pesticides	Liquid chemical product (gal.)	of liquid chemical pesticides
Pesticides	8,773,799	100	1,067,308	100
Disinfectants	1,182,203	13	542,606	51
Disinfectants used on hard surfaces	486,207	6	493,159	46

Source: Prepared by GAO on the basis of data from the PPIS and the FIFRA and Toxic Substances Control Act Enforcement System.

Overview of Efficacy Data Requirements

EPA requires the manufacturer or registrant to develop and submit data on a disinfectant for each claim and use of the product. EPA has published guidelines that recommend specific methods and minimum test specifications for registrants to use to test the efficacy of disinfectants. The guidelines also contain performance standards (pass/fail criteria) that disinfectants must meet to make efficacy claims.

Description of Test Methods

EPA's Pesticide Assessment Guidelines and supplemental technical guidance briefs contain recommended methods for testing disinfectants, standards for conducting acceptable tests, and instructions on interpreting and reporting data. Table 1.3 lists the EPA-recommended methods for demonstrating specific efficacy claims of disinfectants used on hard surfaces.

Table 1.3: EPA-Recommended Methods for Testing Disinfectants Intended for Use on Hard Surfaces

Type of claim	EPA-recommended method(s)	Test organism(s)
Sterilizer	AOAC Sporocidal Test	Bacillus subtilis and Clostridium sporogenes
Tuberculocide	AOAC Tuberculocidal Activity Method	Mycobacterium tuberculosis
	Modified AOAC Tuberculocidal Activity Method	
	Quantitative Tuberculocidal Activity Test Method	
Hospital disinfectant	AOAC Use-Dilution Method	Salmonella choleraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa
	AOAC Germicidal Spray Products Test	
General disinfectant	AOAC Use-Dilution Method	Salmonella choleraesuis and Staphylococcus aureus
	AOAC Germicidal Spray Products Test	
Limited disinfectant	AOAC Use-Dilution Method	Salmonella choleraesuis or Staphylococcus aureus
	AOAC Germicidal Spray Products Test	
Fungicide	AOAC Fungicidal Test	Trichophyton mentagrophytes
	AOAC Use-Dilution Method	
	AOAC Germicidal Spray Products Test	
Virucide	EPA virucidal test parameters	Specific virus claimed
Sanitizing rinse (food-contact surfaces)	AOAC Available Chlorine Germicidal Equivalent Concentration Method	Escherichia coli; and Salmonella typhi or Staphylococcus aureus
	AOAC Germicidal and Detergent Sanitizers Method	
Sanitizer (inanimate, nonfood-contact surfaces)	EPA sanitizer test parameters	Staphylococcus aureus; and Klebsiella pneumoniae aberrant or Enterobacter aerogenes

Source: Prepared by GAO on the basis of EPA's Pesticide Assessment Guidelines.

Most of the EPA-recommended methods were developed under the auspices of the Association of Official Analytical Chemists (AOAC), an independent, international standard-setting organization. AOAC's primary purpose is to develop and validate standardized chemical and biological analytical methods that will perform with the necessary accuracy and precision under usual laboratory conditions to be recognized as "official" methods by the courts and others. According to the AOAC Assistant Executive Director, a collaborative study, or round robin test, is conducted for each method to provide an unbiased evaluation of the performance of an analytical method through the analysis of a number of identical samples by a number of different laboratories.

In evaluating registrant-submitted efficacy data on disinfectants, EPA determines whether the data are adequate to satisfy its data requirements and guidelines. This determination involves considering the design and conduct of the test, including whether generally accepted methods were used, whether a sufficient number of measurements were made to achieve statistical reliability, whether sufficient controls were built into the test, whether the test was conducted in conformity with the design, whether good laboratory practices were observed, and whether the results were reproducible.

Description of Performance Standards

The Pesticide Assessment Guidelines also contain performance standards that EPA requires disinfectant products to meet to make specific efficacy claims. Failure of a product to meet the specified testing or performance requirements is considered evidence that the product is unlikely to be effective as claimed in actual use.

The performance standards vary depending on the claim intended and the test method employed. For example, for a hospital disinfectant, EPA recommends that three batches be tested using the AOAC Use-Dilution Method against three different microorganisms using 60 test tubes per microorganism per batch. If the product fails to kill a microorganism in 2 or more out of the 60 tubes for any microorganism/batch, then the product is considered to have failed the test for the specific microorganism tested.

Disinfectants and Infection Control

Although the role of the inanimate environment in transmitting infections has not been completely defined, doctors, dentists, restaurant owners, consumers, and others consider disinfectants to play an important part in infection control. Health-care providers, as well as others, rely on EPA's registration of disinfectants as evidence that purchased products work as claimed.

Infection control is a serious concern for health-care providers. According to the Centers for Disease Control (CDC), about 5 percent of all patients acquire an infection while hospitalized. Hospital-acquired, or nosocomial, infections prolong hospital stays, increase patient care costs, and, in some cases, cause death. According to one estimate,

nosocomial infections may cause approximately 20,000 deaths and contribute to about 60,000 more deaths annually.⁵ Furthermore, according to one infection control expert, nosocomial infections rank among the 10 most frequent causes of death in the United States.⁶ In addition, interest in disinfectant efficacy has increased in response to the growing numbers of immune deficient patients, who are susceptible to infections.

Although medical experts generally believe that most nosocomial infections are transmitted from person to person rather than from the inanimate environment, the role of the inanimate environment in transmitting infections has not been completely defined. Research has linked at least some infections, including fatalities, to contaminated endoscopes and other medical instruments, but their exact contribution to the overall nosocomial infection rate is unknown. In addition, controversy exists over the extent to which inanimate objects (e.g., stethoscopes) and environmental surfaces (e.g., floors, walls, sink drains) that come into contact with intact skin can transmit infections. Lastly, many infections from inanimate objects may never be detected because so much time can elapse between infection and the onset of illness that the source of the infection is difficult to trace.

Health-care providers generally use disinfectants to treat medical instruments they cannot otherwise sterilize or dispose of. For example, disinfectants are used on sensitive medical instruments, such as fiberoptic endoscopes, that cannot be sterilized using heat and on instruments that need to be sterilized quickly between uses. In addition, many health-care providers view the use of disinfectants on objects/surfaces that come into contact with intact skin as a necessary part of infection control, in the absence of evidence that these objects/surfaces play a negligible role in transmitting infections.

Infection control also is a serious concern in the food-processing and food-service industries, since food can be easily contaminated by disease. The total amount of food-borne illness in the United States is unknown, but outbreaks occur frequently. Both industries use sanitizers on food-contact surfaces (e.g., food-processing equipment and utensils) to reduce the likelihood that food may become contaminated.

⁵James M. Hughes and William R. Jarvis, "Epidemiology of Nosocomial Infections," in Manual of Clinical Microbiology, 4th ed., ed. Edwin H. Lennett et al. (Washington, D.C.: American Society for Microbiology, 1985).

⁶Robert W. Haley, Managing Hospital Infection Control for Cost-Effectiveness (Chicago: American Hospital Publishing, Inc., 1986).

Prior GAO Reports

We have issued two reports in the past addressing the need to better regulate the efficacy of disinfectants. In 1968, we reported that many pesticides subject to enforcement-seizure action, including some disinfectants that the federal government found to be ineffective, may have remained on the market.⁷ In 1974, we questioned EPA's reliance on registrant-submitted data for registering pesticides with high rates of efficacy failures, such as disinfectants. We also found that EPA did not always cancel disinfectant registrations or require registrants to delete efficacy claims from the labels of repeatedly ineffective disinfectants.⁸

Objectives, Scope, and Methodology

In a January 27, 1989, letter, and at subsequent meetings with their staffs, the Chairman and Ranking Minority Member of the House Committee on Government Operations, and the Chairman and Ranking Minority Member of the Environment, Energy and Natural Resources Subcommittee, House Committee on Government Operations, asked us to review EPA's efforts to regulate the efficacy of disinfectants. In particular, the Committee and Subcommittee agreed that we would address the following questions:

- What is the nature of the scientific controversies surrounding EPA-recommended methods for testing the efficacy of disinfectants?
- What action has EPA taken to obtain objective research to resolve the scientific controversies that surround disinfectant efficacy test methods and performance standards?
- Does EPA have sufficient internal controls to ensure the quality and integrity of registrant-submitted disinfectant efficacy data?
- What post-registration enforcement procedures have EPA and the states implemented to ensure that disinfectants on the market are effective?
- Does a need exist for a post-registration program to monitor disinfectants on the market and, if so, what options exist for structuring such a program?

EPA believes that all disinfectants are critical to protecting public health. However, we decided to concentrate our review on EPA's regulation of the efficacy of disinfectants registered for use on hard surfaces because over 75 percent of all disinfectants were registered for use on at least one hard-surface use site. In addition, these disinfectants are most

⁷Need to Improve Regulatory Enforcement Procedures Involving Pesticides (B-133192, Sept. 10, 1968).

⁸Pesticides: Actions Needed to Protect the Consumer From Defective Products (B-133192, May 23, 1974).

affected by the scientific controversies surrounding the test methods used to substantiate efficacy.

To understand EPA's efficacy data requirements and determine the nature of the scientific controversies surrounding EPA-recommended methods for testing disinfectant efficacy (see ch. 2), we (1) reviewed, and interviewed EPA officials about, EPA's disinfectant efficacy data requirements and procedures for accepting test methods, procedures, and modifications; (2) observed microbiologists at two state laboratories perform efficacy tests; (3) interviewed sources knowledgeable about the test methods and controversies, including individuals affiliated with federal and state agencies, standard-setting organizations, professional and trade associations, scientific associations, universities, and commercial laboratories (see app. I); (4) attended several conferences and meetings held by the AOAC, the standard-setting organization whose methods are the subject of scientific controversy, and discussed disinfectant efficacy test methods and related issues with participants; and (5) reviewed scientific and medical literature on disinfectant efficacy and efficacy test methods.

To determine what steps EPA has taken to obtain objective research to resolve the controversies (see ch. 2), we (1) interviewed the EPA grant, project, and quality assurance officers responsible for managing and overseeing EPA's cooperative agreements on efficacy test research with the University of North Carolina at Chapel Hill (UNC); officials within the EPA Antimicrobial Program Branch; and the two lead UNC researchers and the statistician participating in the cooperative agreements; (2) reviewed EPA financial assistance agreement regulations, policies, and procedures; (3) reviewed EPA grant and project officer files and UNC records, including financial statements, progress reports, and technical reports; (4) interviewed individuals outside EPA about the research performed under the agreements; and (5) reviewed EPA's June 1987 strategy paper on improving its disinfectant program and updates to the strategy. We were unable to determine whether EPA had obtained objective research because EPA inadequately managed the cooperative agreements.

To determine whether EPA has sufficient internal controls in place to ensure the quality and integrity of registrant-submitted disinfectant efficacy data (see ch. 3), we (1) reviewed the Federal Managers' Financial Integrity Act of 1982 (FMFIA) and federal guidelines on internal controls, (2) reviewed EPA's 1983 through 1989 annual internal control

reports and other EPA documents on EPA's internal controls, (3) interviewed EPA officials to determine what procedures EPA has implemented to ensure the quality and integrity of the efficacy data that registrants submit and whether the procedures are effective, and (4) reviewed files from EPA inspections/audits over about a 4-year period at laboratories that have conducted disinfectant efficacy studies.

To determine what post-registration procedures EPA and the states had implemented to ensure that disinfectants on the market are effective (see ch. 4), we (1) visited and/or interviewed officials from states that monitor the efficacy of marketed disinfectants and obtained available testing and enforcement data; (2) interviewed several officials representing states that do not test disinfectants to determine why; (3) visited EPA's disinfectant laboratory facility in Beltsville, Maryland and reviewed existing records from the testing program maintained at the lab; and (4) interviewed EPA officials about EPA's decision to discontinue a limited program to test disinfectants for efficacy. To determine which states monitor the efficacy of marketed disinfectants, we relied primarily on EPA to survey the states through the EPA regional pesticide branch chiefs.

To determine whether a need exists for a post-registration program to monitor disinfectants on the market and what options exist for structuring such a program (see ch. 5), we (1) interviewed individuals within EPA, the disinfectants industry, the health-care community, state agencies, and academia; (2) reviewed available disinfectant laboratory cost estimates; and (3) reviewed the history of legislative proposals to resume a disinfectant-testing program at EPA's Beltsville laboratory.

To identify the number of registered disinfectant products and claims and the amount of disinfectants sold in the United States, we used data from EPA's Pesticide Product Information System and FIFRA and Toxic Substances Control Act (TSCA) Enforcement System (FIFRA sec. 7 annual production report data). To identify laboratories that conducted disinfectant efficacy studies submitted to EPA, we used EPA's Pesticide Document Management System. (We will express our concerns about the accuracy and completeness of disinfectants data in these systems in a separate letter to be issued shortly to the Administrator, EPA.)

To understand the role of disinfectants in preventing disease transmission, we (1) reviewed medical literature on disinfectants and infection

control, (2) interviewed representatives from the infection control community and reviewed their infection control guidelines, and (3) interviewed infection control personnel at a large urban teaching hospital about infection control procedures and watched them demonstrate these procedures.

We did not (1) attempt to resolve the scientific controversies about disinfectant efficacy test methods by independently analyzing the validity of the methods, (2) review the efficacy of any individual disinfectant or class of disinfectants, (3) address EPA's efforts to monitor disinfectant efficacy claims made in product advertising, or (4) assess EPA's knowledge and regulation of the toxicity of disinfectants.

Our review was conducted from January through November 1989 and updated with information gathered through June 1990 in accordance with generally accepted government auditing standards. As requested, we did not obtain official agency comments on this report. We did, however, discuss the factual content of the report with EPA officials and have included their comments where appropriate. EPA officials generally agreed with the accuracy of the facts, but believed that as presented the report could be misread, and suggested changes for presenting them. We made some revisions to the report on the basis of EPA's comments and believe that the report is a fair and accurate presentation of the issues.

EPA Lacks Assurance That Efficacy Test Methods Are Valid

Doctors, janitors, consumers, and others rely on EPA's review and approval of registrant-submitted data for assurance that disinfectants work as claimed. However, we found that this reliance may be unfounded because (1) scientific consensus is lacking on the validity of the test methods and standards EPA recommends to registrants for substantiating disinfectant claims and (2) EPA lacks criteria for assessing the validity of registrant-proposed test methods and standards and does not independently validate test methods before permitting their use. We question whether EPA has adequately attempted to resolve the controversies. EPA inadequately managed the limited research that it has funded to help resolve the scientific controversies, and the research has proved to be controversial itself. Further, EPA has made limited progress in conducting additional research to resolve the controversies because of budget constraints.

Scientific Controversy Over Methods and Standards

EPA's regulations require that pesticide registration test methods be statistically reliable, generally acceptable, and reproducible. However, almost all of the EPA-recommended efficacy test methods and performance standards for the approximately 3,200 disinfectants used on hard surfaces have been embroiled in scientific controversy for over a decade. Various scientists and officials from EPA, state governments, academia, industry, commercial laboratories, scientific associations, and user groups disagree over whether

- the test methods contain uncontrollable variables that produce inconsistent and nonreproducible results,
- the existing laboratory test methods adequately simulate performance of a disinfectant in actual use, and
- the performance standards (pass/fail criteria) for existing methods are valid or should be changed.

Although EPA and state officials acknowledge that the existing disinfectant efficacy methods and standards may need to be improved, EPA and certain state officials argue that the existing methods and standards have not been invalidated, are the only available methods/standards, and are acceptable for registration and enforcement purposes. According to these officials, inconsistent test results on possibly marginally effective and ineffective products may be at least as much responsible for the alleged problems with disinfectant efficacy test methods and standards as the methods and standards themselves. Further, several state officials and others believe certain registrants and others have

raised problems with the methods and standards to divert the attention of enforcement review from products that are possibly ineffective.

We were unable to disentangle valid criticisms of test methods and performance standards from possible industry self-interest or possible industry-funded research biases because of the mutually dependent relationship that exists between researchers and industry. EPA does not believe that it registers ineffective disinfectants. However, we found that the validity of EPA's recommended disinfectant efficacy methods and standards has been disputed to such an extent that the credibility and use of these methods and standards to substantiate disinfectant efficacy claims have been impaired.

Variabilities in Test Methods Alleged

Methods recommended by EPA for testing disinfectant efficacy have been widely criticized by industry, academia, and others for producing highly variable results. Researchers disagree over the extent and causes of the variability and over how the methods can be improved or replaced. Industry and other critics have alleged that extreme variability inherent in the test methods and laboratory procedures raise doubts about whether the test results can be repeated within the same lab and whether test results can be reproduced by different labs. Specific controversies related to test variabilities involve questions like the following: (1) Does the design of the methods or the efficacy of products and chemical compounds tested account for inconsistent results? (2) To what extent can variability in laboratory procedures, operator technique and experience, and materials used be controlled or reduced? and (3) Do EPA's recommended methods, some of which were developed over 20 years ago, lack the necessary accuracy and precision expected of test methods today?

Most criticisms have focused on the AOAC Use-Dilution Method and the AOAC Tuberculocidal Activity Method. In fact, the AOAC has actively considered repealing the two test methods during the past 3 years because of reports that results from the test methods could not be consistently reproduced.¹ However, because of similarities in design, concerns about test variabilities in the AOAC Use-Dilution and Tuberculocidal methods

¹The AOAC repealed the Tuberculocidal Activity Method at its general meeting in September 1988. The AOAC Board of Directors reinstated the method in March 1989, following an objection raised by EPA in December 1988 that the AOAC membership voted on the basis of erroneous information presented at the 1988 meeting.

may also apply to other disinfectant efficacy tests, such as the AOAC Sporocidal Test.

Ability of Lab Tests to Simulate Actual Use Questioned

Controversy exists over the extent to which EPA-recommended efficacy tests should and do simulate actual use and whether they provide a sufficient margin of safety to allow for expected variations in actual use conditions. EPA has generally assumed that if a disinfectant fails to perform as claimed under the recommended efficacy tests conducted in a laboratory, then it will fail to perform under actual use conditions. However, critics from industry, academia, and other organizations claim that the laboratory tests may not accurately predict how a disinfectant will perform in actual use because the surfaces, number and resistance of microorganisms, presence of organic matter (e.g., blood), disinfectant concentration, ambient temperature at which a disinfectant is used, and amount of time a disinfectant is exposed to a contaminated surface (referred to as "contact time"), among other things, encountered under actual use conditions may differ significantly from laboratory test conditions. In fact, some infection control experts have advised disinfectant users to extend the contact time on EPA-registered labels to compensate for the unknown margin of safety in EPA-recommended efficacy tests.

Central to the laboratory simulation question is the controversy over carrier-based versus suspension-based disinfectant efficacy test methods.² Scientists disagree over whether carrier-based methods provide a greater representative link between laboratory tests and actual use than suspension tests and whether this purported advantage is offset by an unacceptable increase in variable test results. Further, some scientists question whether labs can bias test results by identifying and selectively using carriers with a higher probability of yielding negative results. Controversy also exists over whether microorganisms are more resistant to chemical disinfectants in carrier-based methods than in suspension-based methods and over whether one type of material used for the carriers is better than another. An industry/state ad hoc group, working under the auspices of the AOAC, and other scientists have recently concluded that carrier-based methods can be refined to reduce variable test results by using different carrier materials (e.g., glass versus stainless steel) and more stringent laboratory procedures. However, other scientists argue whether certain carrier materials, such as

²Carrier methods test a product's effectiveness against a test microorganism dried on a "carrier" (a small cylinder called a "penicylinder"). Suspension methods test a product's effectiveness against a test microorganism suspended in solution. The purpose of the carrier is to simulate the surface on which the product would be used.

glass, truly represent environmental surfaces likely to be treated with disinfectants. They also question whether, even granting that these materials do approximate real surfaces, their use reduces variability to an acceptable level.

Most of the EPA-recommended methods for demonstrating efficacy for various types of disinfectant claims on hard surfaces are carrier-based methods. Although EPA generally prefers carrier-based methods because they presumably have a closer link with reality, it has accepted a few suspension-based methods for disinfectant claims on hard surfaces, such as for tuberculocidal claims, when it has believed that the claims would be as stringent as the claims made on the basis of carrier methods.

Validity of Performance Standards Unknown

Much of the scientific and regulatory controversy over the efficacy test methods focuses on EPA's performance standards (pass/fail criteria) for the methods. Some industry officials and researchers assert that the existing performance standards are invalid and need to be changed. Conversely, EPA believes that the standards are valid for registration purposes, even though these standards were adopted many years ago without the benefit of statistical analyses that would be performed for new standards today. EPA plans to continue using the standards to register disinfectant efficacy claims unless investigations, confirming allegations that they are invalid, show that these standards need to be changed.

According to some industry members, EPA's existing performance standards are too stringent—in the case of the AOAC Sporidical Test, nearly impossible to achieve—and such stringency explains why certain registered disinfectant claims could not be substantiated in collaborative studies and state enforcement labs. Members of industry argue, for example, that EPA's standard for a hospital disinfectant claim is arbitrary. This standard permits only 1 failure out of each set of 60 test tubes when tested by the AOAC Use-Dilution Method against three different microorganisms. Industry members claim that such a standard does not adequately allow for the probability that other factors in the test (e.g., variation in the number of test microorganisms in each test tube, variation in the carriers) could explain why an effective disinfectant might sometimes fail the test.

Some EPA officials believe members of industry have tried to encourage EPA to relax its performance standards to avoid possible enforcement action on ineffective disinfectants. Despite the alleged variabilities in

efficacy test results and stringency in performance standards, the data that EPA receives from registrants rarely show such variabilities or that disinfectants fail to meet existing standards. Researchers and state enforcement labs have been unable to substantiate claims for some registered disinfectants. Further, according to EPA/state officials, certain registered disinfectants have failed state and federal enforcement tests by such a wide margin that the disinfectants tested would be judged ineffective by almost any performance standard. EPA officials and others have suggested that because some types and concentrations of active ingredients yield highly variable test results, disinfectants with these ingredients may need to be reformulated with greater concentrations or with different ingredients, or claim longer contact times. Industry officials counter that increasing the concentration of active ingredients in their disinfectants will increase product costs and toxicity and may not improve the “effectiveness” of the disinfectants in actual use. (We discuss the possibility that some registrants may have selectively submitted data for registration in ch. 3 and the need for post-registration enforcement tests in ch. 4.)

Disagreement also exists over whether and how the existing performance standards should be changed. Some researchers argue that the alleged variabilities in the test methods need to be resolved before the performance standards can be modified since changing the standards to allow for test variabilities may increase the probability that EPA would accept an ineffective product. However, according to members of industry, the standards can be modified on the basis of theoretical calculations while the methods are being improved.

Methods Acceptance Process Inadequate

EPA’s process for accepting disinfectant efficacy test methods has contributed to the controversies surrounding the methods. Over the years, EPA has accepted some disinfectant efficacy test methods and modifications to the methods—usually to register product claims at industry’s urging—that have not been developed and accepted by independent standard-setting organizations. EPA has accepted the methods and modifications on the basis of internal, and in some cases external, scientific peer review and regulatory judgment. However, EPA lacks criteria for assessing the validity of proposed new test methods or significantly modified test methods. Furthermore, although EPA does not independently validate methods and does not require registrant-proposed methods and significant modifications to undergo collaborative testing and evaluation prior to acceptance, EPA scientists told us that they cannot evaluate the validity of new methods or significant modifications

without a laboratory evaluation. EPA's experience in accepting alternative methods for substantiating tuberculocidal and other claims suggests that EPA needs criteria for assessing the validity of registrant-proposed methods and significant modifications, including criteria for determining when laboratory data, such as from a collaborative study, are needed to demonstrate validity.

Lack of Criteria to Assess Validity

Under EPA regulations, registrants may use any test method to demonstrate product performance as long as the test method used meets the purpose of the test standards specified in EPA's Pesticide Assessment Guidelines and provides data of suitable quality and completeness as typified by the methods that EPA recommends in the guidelines. EPA also allows registrants to modify the recommended methods to make them suitable for a particular product claim, such as effectiveness against target microorganisms in the presence of organic matter and hard water. However, under the guidelines, registrants are responsible for demonstrating the validity of the test method or modification selected to substantiate product efficacy. According to the Director, Office of Pesticide Programs, consistent testing with uniform and valid methods is essential for judging the comparability of efficacy test results.

As noted in chapter 1, EPA has primarily relied on the AOAC and other independent standard-setting organizations as sources for the recommended methods published in the guidelines. However, because these organizations have not published methods for demonstrating all types of disinfectant efficacy claims, EPA guidelines do not contain standard methods for demonstrating all types of claims. For example, the guidelines do not contain a standardized method for registrants to use to demonstrate that products are virucidal when used on hard surfaces. Instead, EPA's guidelines contain minimum specifications (parameters) with which registrants must comply to make these types of efficacy claims.

EPA has primarily relied on scientists in the Antimicrobial Program Branch to review the validity of proposed new methods and modifications. In cases where registrants have proposed an alternative method that represents a major departure from existing EPA-approved methods, EPA has consulted the scientific community, including the FIFRA Scientific Advisory Panel,³ the Centers for Disease Control (CDC), and the Food and

³The FIFRA Scientific Advisory Panel is a statutorily created panel of experts convened to review major pesticide decisions or regulations and to give advice to the Administrator, EPA.

Drug Administration (FDA), before accepting the method. However, EPA has not developed written criteria that methods must meet for EPA to consider them valid. Further, EPA has recognized that laboratory evaluations are sometimes needed to assess the validity of new methods and significantly modified methods. In particular, according to EPA scientists, it is difficult for them to determine, in the absence of laboratory evaluations, the extent to which new test methods and significantly modified methods are reproducible and reliable.

EPA officials argue that EPA needs the regulatory flexibility to accept new or alternative methods to respond to changes in infection control needs and product claims. Further, EPA officials claim that collaborative testing of methods prior to acceptance is a lengthy process usually requiring 2 or more years to complete and that EPA lacks the laboratory facilities and personnel to validate registrant-submitted test methods independently. However, EPA officials acknowledge that collaborative testing of methods is scientifically ideal and that reviewing registrant-proposed methods and modifications is an insufficient mechanism for evaluating the comparability of results obtained with multiple methods for substantiating one type of efficacy claim.

Problems With Multiple Tuberculocidal Methods

Since about 1976, EPA has received conflicting reports about the effectiveness of glutaraldehyde-based products when tested by the AOAC Tuberculocidal Activity Method—a carrier-based test. (Glutaraldehyde is one of the most widely used active ingredients for hospital disinfectants.) Researchers from a leading manufacturer of glutaraldehyde-based products submitted evidence to EPA indicating that none of six glutaraldehyde-based products tested, including the manufacturer's product, met their label claims of killing tuberculosis bacteria in 10 or 20 minutes at 20°C (about 68°F) when tested under the AOAC method. The researchers claimed that glutaraldehyde was more sensitive to temperature than previously thought and that variables in the method, particularly the carrier, led to inconsistent and erroneous results. EPA has reported that it obtained similar inconsistencies in its preregistration testing of tuberculocidal products using the AOAC method at its testing facility in Beltsville, Maryland, between 1971 and 1979. In 1983, the industry researchers, also key AOAC officials, submitted a quantitative suspension test, intended to replace the AOAC Tuberculocidal Activity Method, to EPA.

In May 1986, on the basis of internal review and its analysis of two separate FIFRA Scientific Advisory Panel subpanel reviews, EPA concluded

that both the AOAC method and the proposed quantitative suspension method had merit. EPA decided to allow registrants to choose from one of three testing options to substantiate tuberculocidal claims. In June 1986, EPA required registrants of all tuberculocidal products to submit new data to support the claim using the new quantitative method, the AOAC Tuberculocidal Activity Method, or the AOAC method with substantial modification of the contact time and/or temperature. EPA also required registrants of certain chemical classes to submit test data from a second, independent laboratory to validate test results from the first laboratory. (In 1987, the AOAC edited its tuberculocidal activity method to state that the method had not been validated for glutaraldehyde-based products.)

As of February 1989, 44 out of 144 products had satisfied EPA's request for data; the remaining products either deleted their tuberculocide label claims or were suspended or canceled. Of the 44, 11 used the new method, 25 used the standard AOAC method, and 8 used the modified method. The 19 products that relied on either the new method or the modified AOAC method resulted in label claims of either use at higher temperature or different contact time or both.

Although most registrants submitted data using only one of the test options, several registrants developed data using more than one test option. According to EPA, the data indicated that one glutaraldehyde-based product passed both the standard AOAC method and the quantitative method but at significantly different contact times. Under the standard AOAC method, the product was tuberculocidal (i.e., killed 100 percent of the test bacteria) in 10 minutes at 20°C, but under the quantitative method, the product was tuberculocidal in 55 minutes at 20°C. Despite the disparity in test results, EPA accepted the label claim for the product on the basis of the standard AOAC test because it had allowed registrants the option of choosing which test to use. EPA concluded that

There is no technical information available on which to base a scientific judgment of the reason(s) for the significant differences in required contact time for tuberculocidal effectiveness. It is unknown whether the difference is: an unintended confirmation of the questionable efficacy test results alleged to occur when glutaraldehydes are tested by the standard AOAC method; attributable to some deficiency in the quantitative method; or attributable to other testing or product related factors.

EPA has acknowledged that controlled laboratory studies are needed to comparatively evaluate the three test options. EPA has also acknowledged that the quantitative test needs to be collaboratively evaluated.

Despite these limitations, EPA continues to allow registrants to choose from among the three options to support tuberculocidal claims.

Although 7 years have passed since the quantitative method was first submitted to EPA, the agency still lacks definitive, independent laboratory data showing that the AOAC Tuberculocidal Activity Method is invalid or that the quantitative suspension method is valid. In addition, the quantitative suspension test has yet to be collaboratively tested and approved by the AOAC because of statistical design problems and lack of laboratory participation in a collaborative study. EPA has been trying to comparatively evaluate the AOAC Tuberculocidal Activity Method and the quantitative suspension test at its laboratory facilities in Beltsville, Maryland, but the lab has had problems with equipment and with growing the test organism. As part of a 1990 research initiative, discussed below, EPA plans to fund research to assess the validity of the AOAC Tuberculocidal Activity Method.

Other Test Method Problems

The tuberculocide example is not unique. EPA has accepted other disinfectant efficacy methods and significant modifications to methods that have not undergone collaborative studies to validate test procedures. For example, EPA has allowed registrants to modify test methods by adding hard water and organic matter to simulate actual use without knowing how these additions affect the validity of the methods used.

EPA has also accepted similar efficacy claims for different disinfectants on the basis of multiple methods without laboratory data assessing whether the methods yield comparable results. For example, EPA allows registrants to use either a modified form of the AOAC Use-Dilution Method or the AOAC Fungicidal Test to make fungicidal claims. However, in one case, the State of Florida tested and failed a product using the AOAC Fungicidal Test but could not take any enforcement action because EPA had registered the product on the basis of passing test results the registrant had submitted using the AOAC Use-Dilution Method.

Limited Progress Made in Resolving Controversies

Although EPA has known about the scientific controversies surrounding its recommended disinfectant efficacy test methods and standards for most of the last decade, it has not made much progress in resolving the controversies. Between 1983 and 1989, EPA funded limited research to improve disinfectant efficacy methods. However, the research did not

fulfill EPA's objectives because EPA inadequately managed it. Furthermore, although EPA developed a strategy in 1987 to improve the disinfectants program that included, as its most important element, proposed research on test methods, EPA has made limited progress in completing the research because of budgetary constraints. A new research initiative is a step in the right direction, but more work remains to be done.

Research Not Managed Well

Between October 1983 and October 1989, EPA spent about \$384,000 on two consecutive cooperative agreements with the University of North Carolina at Chapel Hill (UNC) to update and improve the AOAC Use-Dilution Method, Tuberculocidal Activity Method, and Sporocidal Test.⁴ UNC researchers investigated 19 presumed deficiencies in the AOAC Use-Dilution Method and conducted two collaborative studies to evaluate variabilities in that method and in a slightly modified version of it. In addition, they conducted preliminary investigations on an alternative quantitative suspension method, conducted preliminary investigations on the AOAC Tuberculocidal Activity Method, and conducted preliminary evaluations of tuberculocidal claims of certain products, as well as other investigations. On the basis of the research conducted, UNC researchers concluded that the AOAC Use-Dilution Method and the slightly modified version were subject to extreme inter-laboratory variability, mostly due to the carrier, and should not be used for registration or enforcement purposes. The researchers recommended that an alternative method, such as a quantitative suspension test, replace the AOAC Use-Dilution Method.

EPA believes that the UNC researchers did not fulfill the primary intent of the cooperative agreements because they focused on examining deficiencies in the AOAC Use-Dilution Method rather than correcting the deficiencies to reduce variability and establish new pass/fail criteria. EPA officials strongly criticized UNC's research conclusions because of a dispute on the relative merits of carrier- versus suspension-based disinfectant efficacy test methods. These officials do not believe that the UNC research results definitively show that the AOAC Use-Dilution Method is valid or invalid because of methodological limitations in the research. They also believe that the research results might reflect deficiencies in registered products rather than irreparable problems with the method.

⁴The total value of the cooperative agreements was \$404,340, with EPA contributing \$383,709 and UNC contributing \$20,631. On February 28, 1990, EPA extended the project period of the second agreement to May 23, 1990, at no cost to the federal government to allow UNC researchers time to complete their final report.

In fact, EPA officials believe that the UNC research showed that the primary source of the alleged variability in the AOAC Use-Dilution Method—the stainless steel carrier—can be mitigated by using glass carriers and has endorsed the efforts of the ad hoc industry/state group to this end. Disappointed with the UNC research, EPA reduced the amount of funding under the cooperative agreement during the last 2 years and delayed funding while deciding whether to continue the agreement.

In their own defense, the UNC researchers pointed out that EPA officials, especially those in the Antimicrobial Program Branch, were not highly critical of the research until 1987, when the AOAC began to consider repealing the AOAC Use-Dilution Method on the basis of the UNC research results. According to the UNC researchers, EPA's criticisms of the research may be the reaction of someone shooting the messenger of bad news. The researchers claimed that EPA officials may be unwilling to accept the prospect that the most widely used disinfectant method, upon which thousands of product claims to protect the public health are based, may be invalid. The researchers further asserted that the cost and administrative burden of reregistering thousands of product claims on the basis of a new method may be prohibitive in the eyes of EPA officials who manage a program already considered to be of lower priority than that of other pesticide programs.

EPA's inadequate management of the UNC cooperative agreements may have contributed to the controversy over the research. Under EPA regulations, a cooperative agreement is a form of financial assistance in which EPA expects to be substantially involved in the project funded. EPA's project officer for the UNC cooperative agreements (the EPA program official designated to manage and monitor the project), also a key AOAC official in disinfectant method development, did not appear to be substantially involved in managing and monitoring the direction and priority of research at UNC to fulfill EPA's research objective. Under the terms of the cooperative agreements, the project officer, in consultation with the UNC researchers, was responsible for determining the nature and scope of tasks performed under the agreements.

The records of the project, grant, and quality assurance officers show that the EPA project officer allowed the UNC researchers to develop the work plans for the cooperative agreements. However, the project officer and other EPA officials later criticized UNC's research direction and the scope of work and tasks UNC performed. For example, the project officer criticized the methodology of UNC's second collaborative study on a modified version of the AOAC Use-Dilution Method after UNC completed the

work. In addition, according to the project officer, he did not insist on the quarterly progress reports the second cooperative agreement called for from UNC because he did not think that sufficient funds were available under the cooperative agreement for UNC to complete these reports.

The dispute between EPA and UNC over the research may have been compounded by a lack of communication and coordination within EPA and a lack of top management involvement in the early years of the cooperative agreements. The EPA project officer for the cooperative agreements worked in the Biological and Economic Analysis Division. This division is separate from the Registration Division, which contains the Antimicrobial Program Branch. Although the UNC research was intended to support the Antimicrobial Program Branch, which registers disinfectants, it appears that the two divisions did not communicate on the scope of work and results of the research, since the Antimicrobial Program Branch did not comment on the cooperative agreement research until 1987.

EPA and UNC have also disputed other issues under the cooperative agreements. EPA has criticized UNC's researchers for investigating the claimed tuberculocidal efficacy of individual products rather than investigating the validity of the AOAC Tuberculocidal Activity Method. EPA has also criticized the UNC researchers for publicizing the results of their research on tuberculocidal disinfectants before sharing them with EPA as required in the second cooperative agreement. In both situations, however, it appears that EPA officials did not closely manage and monitor the cooperative agreement and expressed dissatisfaction with the researchers and research results only after the work was completed and publicized.

We do not know whether EPA's criticisms of UNC's research are valid, reflect reasonable differences in scientific judgment, or reflect a defensive position and lack of acceptance of the research results. However, if EPA is ever to resolve the scientific controversies that surround disinfectant efficacy test methods and performance standards, it must do a better job of managing the research.

Limited Progress in Conducting Planned Research

In response to mounting criticisms from industry, the public-health community, disinfectant users, the Congress, and others, EPA developed a strategy to improve its regulation of disinfectants in 1987, which proposed research on the methods and standards EPA recommends. However, EPA has made limited progress in conducting this research because

of budget constraints. A recent EPA research initiative is a step in the right direction, but it will be several years before EPA fully addresses the controversies surrounding disinfectant efficacy methods and standards. In addition, the regulation of disinfectant efficacy may be hampered by the lack of an adequate, federal laboratory facility to conduct disinfectant efficacy method research and development.

In 1986, EPA convened a multi-office work group to analyze alleged problems with disinfectant efficacy test methods and also hired a microbiologist consultant to provide expertise on the issues. The work group identified deficiencies in several critical areas of the disinfectants program, including those areas embroiled in the scientific controversies discussed above, and explored several approaches for resolving the deficiencies that would not depend on a large-scale, federally operated testing program. The work group concluded that

The most critical and most recognized deficiency is the current lack of credibility of the standard efficacy test methods utilized in the registration program, particularly the AOAC test procedures. Any attempt to improve the [disinfectant] efficacy program is contingent upon re-establishing the credibility of the existing methods; updating/revising the existing methods; or developing new methods.

To resolve the deficiencies, the work group developed a five-point strategy that included improving or replacing existing efficacy methods. The work group estimated that EPA would need about \$1.5 million in contract funds to evaluate the methods.

Between 1987 and 1990, EPA made limited progress in conducting its planned research because of competing program priorities and budget constraints, according to the Chief, Antimicrobial Program Branch. According to a June 1990 strategy update, "Because of budget constraints, EPA's past efforts in conducting evaluations of current test methods have been limited."

Recognizing its resource limitations, EPA challenged industry, user groups, and others to coordinate resources to achieve mutual research goals. In response to this challenge, the aforementioned ad hoc industry/state group, funded by individual participating laboratories, conducted a collaborative study of a new hard-surface carrier test in 1989. EPA officials believe that the study results show that the test, which they consider to be a modified version of the AOAC Use-Dilution Method, is reproducible and reliable. EPA officials expect that the ad hoc group will present its final study report to the AOAC in September 1990 and that the

AOAC will consider replacing the existing AOAC Use-Dilution Method with the new method. EPA will consider what regulatory actions, if any, to take on the basis of the new test after it is considered by the AOAC and after additional research is completed on the effects of using hard water and organic matter in the method and on the appropriate performance standard for the method, according to the Chief, Antimicrobial Program Branch.

In April 1990, EPA announced that it plans to support three cooperative agreements over a 2-year project period to conduct research and development on validating, revising, or replacing the AOAC Tuberculocidal Activity, AOAC Sporocidal, and EPA virucidal test methods and performance standards. EPA plans to spend approximately \$600,000 in fiscal year 1990 funds on this research. EPA plans to award the cooperative agreements by September 30, 1990.

Although EPA's funding initiative represents a substantial increase in commitment to resolve the scientific controversies, the Chief of the Antimicrobial Program Branch believes that the initial funding will be insufficient to resolve the controversies completely. She estimates that EPA may need to spend an additional \$1.2 million to completely research the alleged problems with the methods and standards.

If the new research initiative is not well managed, EPA, industry, disinfectant users, consumers, and the public health will be no better off than they are today. EPA has designated the Antimicrobial Program Branch, within the Registration Division, as the project office for the new cooperative agreements instead of the Biological and Economic Effects Division, which was the project office for the UNC cooperative agreements. Further, EPA has announced that it "intends to be involved in the test methodology research and development by approving work by stages, approving any subcontracts, conducting on-site visits/inspections at reasonable intervals, co-authoring published reports relative to the funded study, and halting research activity if the intent, approach, or anticipated phases leading to the accomplishment of the study are not being achieved, or have been revised without prior Agency approval."

Although this approach may resolve some of the management problems EPA experienced with the UNC cooperative agreements, EPA might want to request that the FIFRA Scientific Advisory Panel provide advice on the research direction and results. EPA's 1987 strategy paper called for the panel's assistance to help evaluate research priorities, among other things, but as of June 1990, EPA had not convened the panel for this

purpose. In addition to guidance on research needs and priorities, the FIFRA Scientific Advisory Panel could provide independent confirmation of the need for any regulatory changes that might be indicated by the research, such as the need to reregister disinfectants on the basis of new methods and standards. An EPA decision to involve the FIFRA Scientific Advisory Panel in this manner would be consistent with the internal control principle of separating key functions in a transaction to ensure that effective checks and balances exist.

Many of the disinfectant efficacy test methods in dispute were developed by scientists working at the federal government's laboratory facilities in Beltsville, Maryland. EPA discontinued testing disinfectants at Beltsville in 1982 primarily because of budget constraints. Although EPA kept the laboratory open to assist in a limited capacity on method evaluation, EPA officials readily admit that EPA lacks the personnel and facilities to do the necessary methodology research. According to the current laboratory supervisor, EPA's Beltsville laboratory facilities would not pass EPA's own good laboratory practice (GLP) regulations. (Ch. 5 discusses options for a disinfectant laboratory.)

Conclusions

Disinfectants are used to reduce the risk of transmitting infectious diseases. If disinfectants fail to work as claimed, then those using disinfectants in restaurants, child day care centers, hospitals, homes, and other places may be placing themselves and others at risk and wasting their money.

Doctors, janitors, consumers, and others rely on EPA's registration of disinfectants as assurance that these products work. However, scientific controversy exists over the validity of the methods and standards that EPA recommends that registrants follow in order to substantiate claims. Although EPA and state officials have accepted allegations that there may be problems with the methods and standards, they believe that the existing methods and standards are acceptable for registration and enforcement purposes. Nonetheless, the scientific controversies over the adequacy of these methods and standards have impaired the credibility of EPA's registration of disinfectant efficacy claims.

Although disinfectant efficacy test methods and performance standards have been embroiled in scientific controversies for over a decade, EPA has made limited progress in resolving them because of inadequate research management and budget constraints. EPA did not manage and monitor its cooperative agreements with UNC well because it lacked

internal communication and agreement on research tasks and results. EPA also has made limited progress in conducting additional research because of budget constraints. In April 1990, EPA announced that it planned to spend approximately \$600,000 for research on the scientific controversies surrounding certain disinfectant efficacy methods over a 2-year period. Although this initiative is significant, more research, requiring time and additional resources, will be needed.

Although we do not expect EPA to ever eliminate all scientific disputes over these methods and standards, the agency could better protect the public health by raising the degree of certainty about the validity of disinfectant efficacy methods and standards. A detailed plan that would describe a research strategy to resolve the controversies surrounding the existing disinfectant efficacy test methods and performance standards would help guide this effort by establishing milestones and cost estimates. In addition, the FIFRA Scientific Advisory Panel could assist in developing the plan and overseeing EPA's research direction and management.

EPA's process for accepting and recommending disinfectant efficacy test methods and standards has contributed to the scientific controversies surrounding methods and standards. EPA has accepted methods and modifications to methods without independent laboratory data that demonstrate the validity of the procedures or standards. Furthermore, EPA lacks criteria for assessing the validity of new methods and any significant modifications to methods. EPA could better ensure that future registrant-proposed disinfectant efficacy methods and modifications are valid by establishing specific criteria for ascertaining validity, including criteria for determining when independent laboratory data, such as collaborative study data, are needed to assess the validity of proposed methods or modifications.

Recommendations

To increase the degree of certainty that disinfectant efficacy test methods and standards are valid, we recommend that the Administrator, EPA, develop a detailed plan, including cost estimates and milestones, to resolve the controversies surrounding existing methods and standards. The plan should include a research strategy that addresses problems with the alleged variability in test methods, adequacy of lab tests to simulate actual use, and the validity of performance standards, as discussed in this chapter. Further, we recommend that the Administrator, EPA, convene the FIFRA Scientific Advisory Panel to assist in developing the plan and overseeing the research strategy direction and

management. (See ch. 5 for options on establishing a laboratory facility to assist in researching and developing disinfectant efficacy test methods.)

In addition, we recommend that the Administrator, EPA, develop and publish a policy that establishes specific criteria for evaluating the validity of new disinfectant efficacy test methods and modifications to methods, including criteria for determining when independent laboratory data, such as data from a collaborative study, are needed to demonstrate the validity of proposed methods and modifications.

Controls Over Quality/Integrity of Efficacy Data Questionable

Even with improvements in its programs to ensure the validity of the test methods used to support the efficacy of disinfectants, EPA would continue to lack assurance that disinfectants work as claimed. EPA relies on registrant-submitted efficacy data to make decisions about whether to register individual disinfectants for specific claims and uses, and on its data review, lab inspection, and data audit programs to ensure the quality and integrity of the data. However, we found weaknesses in these programs that EPA needs to address. We also found that a preregistration-testing program is needed to supplement these programs because they generally do not enable EPA to identify cases in which registrants have selectively submitted incomplete disinfectant efficacy data or have deliberately submitted invalid data. We believe EPA's lack of sufficient control over the quality and integrity of registrant-submitted disinfectant efficacy data is a material weakness in EPA's internal controls that should be, but has not been, reported to the President, as required by the Federal Managers' Financial Integrity Act of 1982 (FMFIA).

Weaknesses Impair Data and Lab Reviews

EPA reviews registrant-submitted disinfectant efficacy data to determine whether proposed label claims are supported by the data and whether registrants have made any major mistakes in performing efficacy tests, interpreting test results, or translating the results into label claims, according to the Head, Efficacy Evaluation and Technical Management Section, Antimicrobial Program Branch. In addition, EPA inspects the labs that generate the data and audits laboratory study records to assess the quality and integrity of the data and the competence of the laboratories that have performed the studies. However, we found that: (1) EPA has inspected/audited only about 10 percent of all of the labs that performed disinfectant efficacy studies submitted to EPA over about a 4-year period and has identified only about 13 percent of all the labs that performed these studies; (2) EPA inspectors and auditors may be unable to evaluate adequately the capability of labs to perform these studies; (3) EPA has been slow to prepare and process reports from inspections and audits at labs performing these studies; and (4) EPA lacks program guidance for conducting data reviews, lab inspections, and data audits relating to these studies.

Not All Labs Inspected

The Laboratory Data Integrity Assurance Division (LDIAD), within the Office of Compliance Monitoring (OCM), is responsible for, among other things, inspecting laboratories that perform studies submitted to EPA to support pesticide registrations and for auditing these studies. The objectives of good laboratory practice (GLP) inspections are to ensure that a

lab follows specific test methods, adheres to standard operating procedures, keeps records in compliance with GLP regulations, and conforms to required safety and quality assurance procedures so that lab practices do not compromise the quality and integrity of data submitted to EPA for registration purposes.¹ The objectives of data audits are to ensure that the data underlying a study are both present at the lab and fully substantiate the study results by comparing the data from the study submitted to EPA with records on the study in the lab. A data auditor typically audits a study at the same time that an inspector inspects the lab that performed the study. LDIAD's goals are to inspect all labs performing efficacy studies approximately every 2 years, audit one or more efficacy studies from each lab inspected, and inspect high-volume labs first.

Between January 1, 1985, and September 30, 1989, LDIAD conducted 13 lab inspections and 14 data audits at 9 individual labs that performed disinfectant efficacy tests. These 9 labs represent only about 10 percent of the 92 labs that had generated disinfectant efficacy data received by EPA between January 1, 1985, and June 26, 1989. The 9 labs that LDIAD inspected generated an estimated 40 percent of the 1,148 disinfectant efficacy studies that EPA received during that period. LDIAD audited 109 studies at the 9 labs.

LDIAD did not inspect most of the labs that had performed disinfectant efficacy studies. In fact, LDIAD identified only 12 (about 13 percent) of the 92 labs that had performed these studies. LDIAD was unaware of most of the labs, including some high-volume labs, because it had not used EPA's Pesticide Document Management System (PDMS) to identify labs for inspections/audits. This system is a central archive primarily consisting of documents that registrants have submitted to EPA to support pesticide registrations, and we used it to identify labs that had performed disinfectant efficacy studies submitted to EPA.

Lab Capability Not Adequately Assessed

Existing EPA program guidance specifies that lab inspections are performed while a study is in progress, that they provide the inspector with an opportunity to observe laboratory techniques, and that they ensure that labs follow specific test methods correctly. Various officials from

¹In August 1989, EPA published GLP regulations governing efficacy studies. These regulations became effective on October 16, 1989. Before this date, EPA could not enforce good laboratory practices of laboratories that performed disinfectant efficacy tests.

EPA, the states that operate disinfectant efficacy testing programs, commercial labs, and industry, as well as the AOAC, have stated that the results of a disinfectant efficacy test are very sensitive to small variations in the way the technician performs the test procedures and that lab personnel must have extensive experience to perform disinfectant efficacy tests correctly. However, according to a June 1987 EPA strategy document, many of the labs testing disinfectants for efficacy do not follow prescribed, standard efficacy test methods.

Although the tests are operator-sensitive, lab inspectors and data auditors generally do not observe disinfectant efficacy tests in progress because EPA has no means of identifying most of the studies ultimately submitted to EPA while they are still in progress, according to the Chief, Scientific Support Branch, LDIAD. In addition, the branch chief told us that disinfectant efficacy tests generally are so short in duration that it is difficult for LDIAD to schedule an inspection at a lab performing such a test before the test is complete. One EPA efficacy data auditor told us that inspectors and auditors do not usually see labs performing efficacy tests because most labs do not run efficacy tests on a continuous basis.

The five EPA data auditors who have audited disinfectant efficacy studies, as well as state lab officials and researchers, told us that a check sample program could ensure the quality of the data registrants submit better than data audits can. EPA currently requires states that have cooperative pesticide enforcement agreements with EPA to participate in a check sample program. Under the program, EPA sends the state labs samples of pesticide formulations and residues for analysis to ensure that they perform analytical tests correctly. EPA could adopt a similar program for laboratories that conduct disinfectant efficacy studies to ensure that they are capable of performing efficacy tests correctly. Under the program, EPA would send samples of formulations of known efficacy to a lab, ask the lab to test the samples for efficacy, then check the lab's results against the known efficacy of the samples.

Processing Inspection/ Audit Reports Takes Nearly Five Times Longer Than Estimated

LDIAD's target time frame for conducting inspections and audits and processing reports is 112 days (about 3.5 months). However, LDIAD had, as of November 13, 1989, taken 539 days (about 1.5 years) on average to perform and process reports from inspections/audits at labs performing disinfectant efficacy studies.² The times ranged from 161 to 963 days (about 5 months to over 2.5 years). The 5 inspection/audit reports that remained open as of November 13, 1989, had been open an average of 360 days. The longest report had been open over 1.5 years since the lab was first inspected.

LDIAD has been slow in processing these lab inspection and data audit reports for three reasons, according to the Chief, Scientific Support Branch. First, most lab inspectors and data auditors are not directly accountable to LDIAD. Instead, most lab inspectors are stationed in EPA's regional offices and have other noninspection-related duties that the regional offices consider of higher priority than the duty of preparing lab inspection reports. Second, according to this official, until recently, the EPA headquarters staff available to perform inspections and process inspection/audit reports at EPA headquarters was too small. Third, EPA did not have enforceable GLP regulations for efficacy studies until October 16, 1989, so LDIAD considered processing inspection/audit reports relating to labs performing these studies to be a low priority. The Director, LDIAD, acknowledged that EPA has been slow in processing inspection/audit reports related to disinfectant efficacy studies as well as other types of registration studies. To address the problem, LDIAD is developing a simplified reporting format and a procedure for processing those reports that indicate a violation first.

Program Guidance Lacking

Scientists in the Antimicrobial Program Branch review registrant-submitted reports summarizing the results of efficacy tests before registering disinfectant efficacy claims. As of June 1990, EPA had not completed final guidelines for these scientists to use in conducting efficacy data reviews, although it had prepared guidelines for performing reviews of most other types of pesticide registration data (e.g., chemical, toxicological, environmental, and ecological data). With such guidelines, EPA could better ensure that its reviewers identify all potential problems with efficacy data. EPA could not estimate when final guidelines would be published.

²This finding is based on the 9 of 10 inspection/audit reports EPA had prepared and completely processed as of November 13, 1989, and for which EPA could provide information.

Similarly, as of June 1990, EPA had not developed guidance for conducting inspections and data audits at labs that have performed disinfectant efficacy studies. Instead, according to the Chief, Scientific Support Branch, LDIAD, inspectors have been using EPA's manual governing inspections at labs that have performed health-effects studies. According to this official, EPA's efficacy data auditors have relied on their professional judgment to perform the audits. (Although two of the auditors have developed questionnaires for use in conducting efficacy data audits, not all five use them.)

In addition, as of June 1990, EPA had not published guidelines specifying the types of inspection/audit findings that would prompt registration and/or enforcement action by EPA and the type of action EPA should take in each case. Although the Registration Division has developed a standard operating procedure for managing the review and disposition of inspection/audit reports, the procedure does not specify criteria for evaluating what registration action, if any, the division should take on the basis of report findings. An LDIAD work group has developed interim guidelines on taking enforcement action that are undergoing internal review.

Preregistration Testing Needed to Ensure Data Integrity

Even if the weaknesses we found in EPA's data review, lab inspection, and data audit programs were corrected, the programs generally would not enable EPA to identify cases in which registrants have selectively submitted incomplete disinfectant efficacy data. EPA's position is that registrants are required by FIFRA to submit all data indicating that a disinfectant may not be effective as registered when registrants are aware that such data exist.³ Evidence exists that some registrants have submitted to EPA efficacy test data indicating that their disinfectants work but may have withheld other test data indicating that these disinfectants do not work as claimed. Furthermore, if a registrant deliberately

³Section 6(a)(2) of FIFRA states:

"If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator." 7 U.S.C. sec. 136d(a)(2).

As interpreted by EPA, "unreasonable adverse effects on the environment" include information concerning the efficacy of disinfectants. Under an EPA regulation, 40 C.F.R. sec. 152.50(f)(3), an applicant for registration also must submit any information that would be required under sec. 6(a)(2) if the product were registered.

submitted invalid data to EPA, or a commercial lab deliberately submitted invalid data to a registrant, EPA's data reviewers, lab inspectors, and data auditors probably would be unable to tell.

Although EPA maintains that FIFRA prohibits registrants from submitting selective data, EPA-recommended methods for testing disinfectant efficacy provide registrants with an opportunity to submit efficacy data selectively. Given the alleged variability in certain disinfectant efficacy tests (see ch. 2), a registrant and/or testing facility could run an efficacy test repeatedly until the formulation tested passed, and the registrant could submit only the passing results to EPA (i.e., a registrant could submit selective data to EPA).

Despite this opportunity, EPA's existing programs for validating efficacy data generally do not enable EPA to recognize selective data. According to the Head, Efficacy Evaluation and Technical Management Section, Antimicrobial Program Branch, data reviewers cannot identify situations in which EPA has received selective data because the reviewer sees only what was submitted rather than all tests conducted on a disinfectant. According to EPA's five efficacy data auditors, data auditors generally cannot identify cases in which registration data are selective. The auditors told us that they rely on labs to identify the records they should audit, and labs could provide them with selective records.

During the course of our review, we found some evidence that registrants have submitted selective data to EPA. For example, one data auditor found evidence of selective data during a data audit—passing and failing data on a high-volume, household product whose registration file contained only passing data. According to the data auditor, he found the set of failure data by chance. The data auditor who discovered the set of failure data and other efficacy data auditors told us that they would have no way of knowing if a registrant withheld data from an audit. In addition, representatives of two registrants told us that they had obtained variable (both pass and fail) efficacy results on disinfectants but had submitted only passing results.

The belief that registrants submit selective data to EPA is widespread. The Chief, EPA Antimicrobial Program Branch, and the Head of the branch's Efficacy Evaluation and Technical Management Section told us they believe that registrants submit selective data, and EPA's June 1990 disinfectant program strategy paper stated that "the practice of not reporting failing/adverse test results is widespread." In addition, other EPA officials, state officials, the UNC researchers, and others all told us

that they believe some registrants submit selective data. In fact, members of the disinfectant industry openly joked about submitting selective data to EPA at a widely attended national meeting on disinfectant efficacy test methods that we and EPA officials attended in 1989. As noted in chapter 2, registrants have argued that the existing test methods yield variable results and the performance standards are too stringent. However, these criticisms, and the fact that EPA rarely receives data showing that disinfectants do not work, suggest the possibility that some registrants could have submitted selective data to EPA to register their products.

Even if the variabilities in the test methods were reduced to limit a registrant's opportunity to submit selective data, neither lab inspectors nor data auditors can practically observe these tests in progress, and no physical evidence (e.g., test tubes) remains from the tests once they are completed. As a result, data reviewers and auditors must rely on the registrant's word about the procedures followed in a test, the disinfectant formulation tested, and the test results, according to EPA officials. In the event that a registrant or lab facility were deliberately to deviate from an EPA-approved efficacy test method (e.g., by running the test at a higher temperature than reported); run a test with a disinfectant formulation that would pass the test, rather than the formulation the registrant planned to market; or record that a disinfectant formulation passed an efficacy test when the formulation failed, data reviewers or auditors probably would not be in a position to identify the deviation and question the test results.

Although a program to test disinfectants before registering them could resolve these issues, EPA does not currently operate such a program. At one time, EPA operated a limited preregistration-testing program to verify sporicidal claims and selected tuberculocidal claims. EPA discontinued preregistration tuberculocidal testing in 1979 because of inconsistent test results and discontinued all other preregistration tests in 1982. EPA's records from the testing program show that at least some registrants changed proposed efficacy claims on the basis of EPA's tests to make them more protective (e.g., lengthened contact times). For example, one registrant lengthened its proposed exposure period for the sporicidal efficacy of a disinfectant from 5 hours to 10 hours in 1974 after the disinfectant failed a preregistration test. EPA would not need to test all disinfectants for efficacy before registering them. Instead, EPA could target such a program to those disinfectant claims of greatest importance to public health, such as sporicidal claims, to those products

with suspected efficacy problems, and/or to other products as determined by the Administrator.

Internal Controls Inadequate

EPA's inability to ensure the quality and integrity of registrant-submitted disinfectant efficacy data is, in our opinion, a material weakness in internal controls under FMFIA. Under FMFIA, each federal agency must establish and maintain a system of internal controls to provide reasonable assurance that, among other things, program and administrative activities are effectively managed to achieve the goals of the agency.

GAO and the Office of Management and Budget guidance on internal controls require agencies to identify, in writing, objectives for each agency activity that are specific, complete, logical, and applicable to the specific activity; as well as techniques that will provide reasonable assurance that the objectives will be accomplished. In addition, federal agencies are required to identify, in an annual report to the President, material weaknesses in internal controls. A material weakness exists in an agency's internal control systems when, among other things, the agency lacks reasonable assurance that the objectives of the system are being accomplished and that the weakness would significantly impair the fulfillment of the agency's mission and/or would deprive the public of a needed service.

Conclusions

EPA relies on registrant-submitted data to support disinfectant efficacy claims. As noted in chapter 2, we found that the validity of disinfectant efficacy methods and performance standards has been questioned and that EPA's process for accepting test methods is inadequate. However, even if EPA addressed these problems, we believe that EPA still would lack sufficient controls to ensure the quality and integrity of registrant-submitted disinfectant efficacy data.

We found a number of weaknesses in the data review, lab inspection, and data audit programs. First, EPA has not identified all labs that have performed disinfectant efficacy studies to be inspected/audited. EPA should use the Pesticide Document Management System which, though limited, contains the best available information for identifying these labs. Second, EPA's lab inspection and data audit programs are unable to completely assess the capabilities of labs that perform disinfectant efficacy tests because these tests are operator-sensitive and inspectors/auditors generally do not observe them in progress. A check sample program could provide EPA with greater assurance that laboratories that

perform these tests for registrants are capable of performing them correctly. Third, EPA has been slow to prepare and process reports from inspections/audits related to disinfectant efficacy studies. The timeliness of these reports is more important now that EPA's GLP regulations encompass disinfectant efficacy studies. A review of OCM's internal controls for ensuring that inspections/audits are processed on time could prevent problems with timeliness in the future. Fourth, EPA has not published guidelines needed to ensure that data reviewers, lab inspectors, and data auditors identify all potential problems with disinfectant efficacy studies and that EPA takes appropriate registration and/or enforcement action.

Although EPA can improve its data review, lab inspection, and data audit programs, we believe that the only way for EPA to determine whether a registrant has submitted selective data or has deliberately submitted invalid data is by testing the product. Evidence exists to suggest that, in at least some cases, pre-registration government tests to verify sporicidal efficacy data led to more protective label claims. We are not suggesting that EPA test all disinfectants for efficacy before registering them. Instead, EPA could target such a program to those disinfectant claims of greatest importance to public health and/or products with suspected efficacy problems. Data reviews, lab inspections, and data audits cannot ensure the integrity of registrant-submitted data. A preregistration-testing program would complement those activities and better ensure the integrity of the data.

We believe that EPA's lack of sufficient controls to ensure the quality and integrity of registrant-submitted disinfectant efficacy studies is a material weakness in EPA's internal controls that should be, but has not been, reported to the President as required by FMFIA. Until this weakness is corrected, EPA may be compromising public health by registering ineffective products.

Recommendations

To improve EPA controls over the quality and integrity of registrant-submitted data, we recommend that the Administrator, EPA, implement a preregistration-testing program to verify selected disinfectant efficacy data. (See ch. 5 for a discussion of options for establishing a laboratory facility to assist in such a program.) The Administrator could target preregistration tests on those claims that are of the greatest public health significance and/or products with suspected efficacy problems.

To improve the effectiveness of the data review, lab inspection, and data audit programs, we recommend that the Administrator, EPA,

- direct the Laboratory Data Integrity Assurance Division to identify all laboratories that have performed efficacy studies submitted to EPA to support disinfectant registrations and meet the division's goal of inspecting these labs at least every 2 years (at a minimum, direct LDIAD to use the Office of Pesticide Programs Pesticide Document Management System, which contains the best available information for identifying the labs);
- direct LDIAD to establish a check sample program as part of the lab inspection program to better assess the ability of labs to perform disinfectant efficacy tests;
- direct the Office of Compliance Monitoring to review its internal controls for ensuring that inspections/audits are processed on time (for example, ensure that inspectors/auditors are held accountable in their performance standards and appraisals for meeting processing time frames); and
- direct the Office of Pesticide Programs and the Office of Compliance Monitoring to develop and implement specific guidance for data reviewers, lab inspectors, and data auditors to follow; further, direct these offices to develop, publish for comment, and implement detailed policies and guidelines to decide what registration and/or enforcement action to take on the basis of findings from lab inspections and data audits.

We recommend that in his next annual internal control report to the President, the Administrator, EPA, report the lack of sufficient controls to ensure the quality and integrity of registrant-submitted disinfectant efficacy data as a material weakness. We also recommend that the Administrator, EPA, include in his report a plan delineating specific corrective actions and time frames.

Limited Monitoring/Enforcement of Registered Disinfectants

Even were EPA to implement improvements in its processes for registering efficacy claims (e.g., independent validation of test methods and preregistration testing), these improvements would not provide sufficient assurance that disinfectants on the market were effective. Registrants could, intentionally or inadvertently, manufacture and sell ineffective batches of disinfectants after registering them. EPA lacks assurance that, once registered, disinfectants work as claimed because EPA stopped monitoring disinfectants on the market for efficacy in 1982. Because states and disinfectant users generally do not monitor disinfectants for efficacy, EPA is relying, in effect, on the industry to regulate itself. Despite the scientific controversies over efficacy test results, historical enforcement and other data suggest that as many as 20 percent of the disinfectant batches on the market do not work as claimed. As a result, disinfectant users may be placing themselves and others at risk from infection and spending money unnecessarily.

Federal Enforcement Testing Discontinued

Until 1982, EPA operated a limited post-registration testing program to verify certain efficacy claims of marketed disinfectants at its laboratory facilities in Beltsville, Maryland. According to the best available information, the program was limited in size, scope, and operation. EPA discontinued the program because of budget constraints and expected that states, users, and the disinfectants industry would assume most of its responsibility for ensuring the efficacy of marketed disinfectants.¹

From 1970, after EPA was established and took over the pesticide programs from the U.S. Department of Agriculture, through 1982, the Beltsville laboratory tested, on average, 207 disinfectant samples annually. However, the number of samples tested each year dropped substantially after 1972. From 1970 through 1972, the laboratory tested an average of 610 samples annually. By contrast, from 1973 through 1982, the laboratory tested an average of 127 samples annually, testing only 47 samples in 1982. Furthermore, the Beltsville laboratory did not verify all types of efficacy claims. According to the microbiologist at the laboratory, the laboratory tested no products from the marketplace for sporicidal claims and, after the mid-1970s, few products for use on surfaces other than hard surfaces.

¹ Although EPA discontinued post-registration testing, it kept the Beltsville laboratory open for use on an as-needed basis (e.g., to perform confirmatory efficacy tests on disinfectant enforcement samples from the states).

According to EPA congressional testimony, EPA discontinued its post-registration testing program primarily because (1) the level of testing was inadequate and was creating a false sense of security among users and the public about the efficacy of disinfectants on the market and (2) budget constraints prevented EPA from conducting what it considered to be an adequate level of testing. EPA officials believed that by discontinuing the testing, EPA could direct more time and effort to evaluating and improving the test methods. EPA officials believed that the states, the user community, and the disinfectants industry would take a more active role in monitoring the efficacy of disinfectants on the market and that EPA could establish a system for processing complaints from these sources about actual or suspected product failures.

However, EPA had little reason to expect that states and disinfectant users would assume EPA's responsibility for monitoring disinfectant efficacy or to assume that a complaint system would be developed because of a lack of EPA leadership. Few states and no users were testing at the time, and no others expressed an interest in testing. In addition, without a laboratory facility or provision to contract for laboratory services, EPA had no mechanism for channelling and verifying complaints about potentially ineffective disinfectants from the states, user groups, and the industry and for initiating appropriate enforcement action against disinfectants found to be ineffective.

Nonfederal Testing Limited

Although EPA discontinued its efficacy-monitoring program in 1982, nonfederal monitoring efforts remain limited. As of July 1989, we were able to identify only three states—Florida, North Carolina, and Mississippi—that were monitoring the efficacy of disinfectants in the marketplace under their pesticide enforcement programs and only two states—Wisconsin and Virginia—that were testing disinfectants under other state programs. Furthermore, we did not identify any users or related groups, including the health-care, restaurant, or food-processing industries, that have implemented comprehensive, routine monitoring programs. In effect, EPA has left the burden of monitoring disinfectant efficacy to the industry itself.

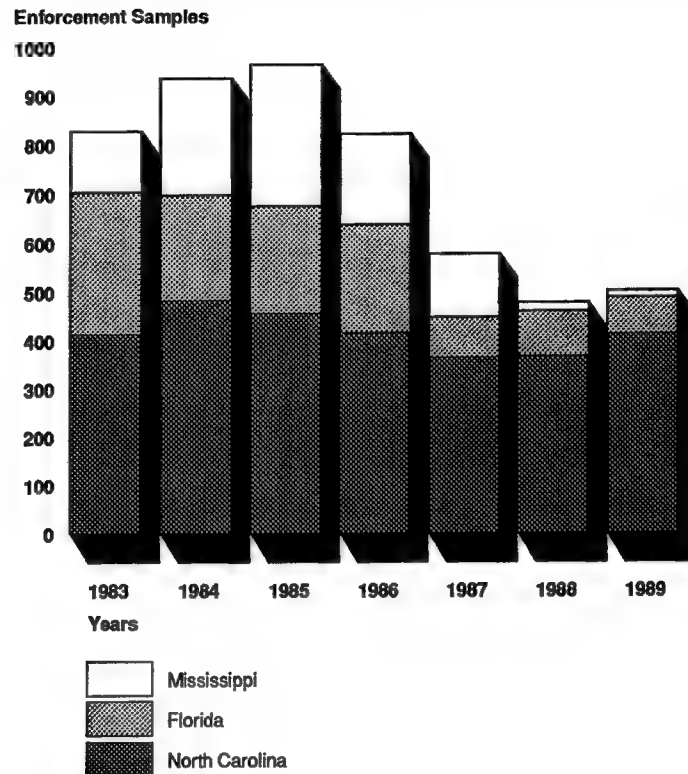
State Testing Limited

Although Florida, North Carolina, and Mississippi monitor the efficacy of disinfectants on the market, the scope of their testing programs and authority of their enforcement programs are limited, and the amount of testing they have performed has decreased in recent years. In addition,

scientific controversies surrounding the test methods have affected their efforts to enforce the efficacy of disinfectants on the market.

The types and amounts of enforcement testing the states perform is limited. Florida, North Carolina, and Mississippi do not verify all types of disinfectant efficacy claims. For example, none tests products for sporicidal, tuberculocidal, or virucidal efficacy. According to officials in these states, the tests are too time-consuming and expensive. Furthermore, the total amount of enforcement testing these states have performed has been dropping overall since EPA discontinued its testing program. The total number of samples the states tested decreased from 962 in 1985 to 500 in 1989. (See fig. 4.1.) The state of Mississippi has virtually discontinued testing. In fiscal year 1989, the state tested only 14 disinfectant samples for efficacy.

**Figure 4.1: Disinfectant Enforcement
Samples Tested by North Carolina,
Florida, and Mississippi, 1983-89**



Florida and Mississippi data are for fiscal years (July 1 through June 30). North Carolina data are for calendar years.

Source: Prepared by GAO on the basis of data from the states of North Carolina, Florida, and Mississippi.

To some extent, the scientific controversies surrounding the test methods and performance standards have affected the states' efforts to enforce the efficacy of disinfectants on the market. For example, the state of Florida has not attempted to issue complaints against any registrant whose disinfectants have failed efficacy tests since 1986. According to the Director, Florida Division of Inspection, the state does not feel comfortable basing legal action on results from efficacy tests until controversies surrounding the AOAC Use-Dilution Method are resolved.

Although Florida, North Carolina, and Mississippi have tested and failed at least some disinfectants registered for use in other states, states do

not have authority to regulate the efficacy of disinfectants in the marketplace outside of their boundaries. In at least two cases, registrants have responded to state enforcement action by recalling disinfectants from the marketplace and disinfectant users within the state or by deleting specific efficacy claims from disinfectant labels, but have continued to market the disinfectants or make the claims in other states. In one case, a producer agreed to recall from a single state market a phenolic-based disinfectant marketed under nine different brand names after the product failed state efficacy tests. However, the disinfectant, which is registered for use on floors, walls, and other hard surfaces in hospitals, nurseries, rest rooms, telephone booths, and elsewhere, continues to be sold in all other states, according to the registrant's customer service representative. In the other case, the registrant of two nationally marketed disinfectants removed claims that the products were effective in hard water from the product labels in one state after one of the products failed state efficacy tests. However, the registrant continues to market the two products (one of which is for use on floors, walls, basins, and on instruments in hospitals, nursing homes, schools, and medical and dental offices) with the claims in other states, according to the registrant's customer service representative.

States other than Florida, North Carolina, and Mississippi have been reluctant to start testing programs. We interviewed officials from several of the states with high pesticide enforcement funding from EPA and/or a high number of disinfectant producers located within their boundaries. The most common reason they offered for not operating testing programs was that they do not have the resources needed to establish and operate a testing facility. Although EPA has provided most states with funding for pesticide enforcement activities, the amount of funding decreased by about 25 percent in real terms (i.e., after adjusting for changes in price levels) from federal fiscal year 1983 to 1989, and, according to the Chief, EPA Grants and Evaluation Branch, EPA has not required the states to make disinfectant efficacy testing a pesticide enforcement priority. Instead of a testing program, most of these state officials said they rely on EPA's judgment in registering disinfectants as assurance that they are effective.

The states of Wisconsin and Virginia operate testing programs but not under their pesticide enforcement programs. The Wisconsin Department of Health and Social Services requires the efficacy of sanitizers intended for use on food contact surfaces (except those containing inorganic hypochlorites) to be tested under its program to regulate the milk and restaurant industries. The Commonwealth of Virginia discontinued an

enforcement testing program sometime around 1982 because, according to the Supervisor, Virginia Office of Pesticide Regulation, the state found that the AOAC Use-Dilution Method did not yield results that were reproducible enough to take enforcement action against registrants whose samples failed the test. Despite problems with the method, the state has continued to test disinfectant samples that manufacturers submit in order to compete for state contracts for some types of efficacy claims.

User Programs Not Established

Individuals and organizations both within and outside of the health-care industry told us that they were not aware of any hospitals, doctors, or dentists that test disinfectants for efficacy. According to several health-care representatives, hospitals and other users do not have the resources and/or the expertise necessary to operate a program to monitor the efficacy of disinfectants on the market. Instead, they rely on EPA's registration of disinfectants as assurance that disinfectants on the market are effective. Furthermore, restaurants and food-processing facilities do not test the sanitizers they use for efficacy, according to representatives from these industries.

Some researchers affiliated with users (as well as others) have tested disinfectants, or are planning to test disinfectants, but have not established monitoring programs. For example, since 1976, Clinical Research Associates, an independent research organization dedicated to evaluating dental materials, devices, and concepts, has been testing the efficacy of selected disinfectants used by dentists. As of February 1990, we had identified two organizations, the American Dental Association (ADA) and the National Sanitation Foundation (NSF), that were considering testing disinfectants for efficacy. However, if ADA were to test disinfectants, ADA would only test tuberculocidal disinfectants and would not test products routinely. Moreover, both programs would depend on voluntary participation by registrants.

Although several individuals and organizations affiliated with disinfectant users have complained or submitted data to EPA indicating that specific disinfectants do not work as claimed, EPA has not established the system for processing these complaints that it proposed as part of its 1987 disinfectant program improvement strategy. Furthermore, EPA has not yet addressed the question of how it would verify the complaints and take appropriate enforcement action against disinfectants found to be ineffective.

Industry Self-Regulation Limited

The burden of monitoring the efficacy of disinfectants has fallen on the industry itself because EPA no longer tests disinfectants, few states test and their programs are limited, users do not generally test, and EPA lacks an effective complaint system. However, market forces cannot be relied upon to control disinfectant efficacy problems because users cannot visually identify ineffective products. Furthermore, although registrants can test competitors' products and have challenged competitors' claims, EPA has been unable to resolve conflicting claims because it lacks the laboratory facilities necessary to do so, according to the Chief, Anti-microbial Program Branch. Consequently, industry self-regulation appears limited. A June 1990 update to EPA's June 1987 strategy paper on improving the disinfectant program acknowledged that some registrants make unregistered and/or exaggerated efficacy claims for disinfectants and that some registrants market unregistered disinfectants.

Some Marketed Disinfectants May Be Ineffective

Although the scientific controversies surrounding disinfectant efficacy test results discussed in chapter 2 cloud the issue somewhat, historical data on specific products from EPA and the states, along with data from industry, academia, and other sources, indicate that some disinfectants on the market are ineffective. Although the true percentage of ineffective disinfectants on the market is unknown, EPA acknowledged in 1983 that as many as 20 percent of marketed disinfectants may be ineffective. Consequently, public health and consumer welfare may be at risk from disinfectants that do not work as claimed.

Historical test-failure data indicate that EPA and the states have been unable to substantiate disinfectant claims for certain products. Between 1978 and 1982, the last 5 years during which EPA tested disinfectants, an average of 42 percent of all disinfectant samples tested by the lab failed efficacy tests. In the years since the EPA lab closed (1983-89), 22 percent, 4 percent, and 2 percent of all disinfectant samples tested by the states of Florida, North Carolina, and Mississippi, respectively, have failed efficacy tests. During 1988 and 1989, about 30 percent of all sanitizer samples tested under the state of Wisconsin program failed, and about 40 percent of the samples tested by the Commonwealth of Virginia failed.

Although many products have failed disinfectant efficacy tests in EPA's and the states' laboratories, the data generally are not comparable. More specifically, EPA and the states have used different schemes for sampling disinfectants from the marketplace, used different performance standards to assess efficacy, and tested different types of claims. For

example, Florida has focused on sampling and testing disinfectants that frequently fail efficacy tests and/or are intended for hospital use, whereas Mississippi has tested products at random from the marketplace. North Carolina and Florida have used pass-fail criteria for disinfectants in efficacy tests that are more lenient than EPA's registration standards. Mississippi has not tested disinfectants for efficacy in the presence of organic matter, while Florida has. Virginia tests disinfectants to determine whether they are effective in hard water and in the presence of organic matter regardless of whether the products are registered with those claims.

While the data from state and federal enforcement testing are not comparable, they suggest that an unknown number of disinfectants on the market may be ineffective. Some disinfectants have failed enforcement tests by a wide margin. At least two states have found disinfectants contaminated with bacteria. Some disinfectants have failed efficacy tests repeatedly in a single state, in multiple regulatory labs (state and/or EPA), or tests performed by registrants themselves at regulatory labs. For example, a disinfectant registered for use on floors, walls, showers, and other surfaces in hospitals, nursing homes, and schools failed efficacy tests on multiple occasions in EPA's lab and two state laboratories. Similarly, a disinfectant registered for use in hospitals, nursing homes, food-processing facilities, office buildings, schools and recreation facilities failed 28 efficacy tests in one state from 1983 to 1988.

In addition, data from industry, academia, and others also raise questions about whether some disinfectant batches in the marketplace work as claimed on their labels. For example, in a collaborative study of the AOAC Use-Dilution Method, three of four disinfectant manufacturers' laboratories unknowingly tested and failed their own products.

While several officials from EPA, industry, and the states, and most others we talked to believe that disinfectants on the market are generally effective, various sources estimate that between 5 to 20 percent of disinfectants on the market do not work as claimed. EPA officials, themselves, believe that some disinfectants on the market may be ineffective. In 1983, the Director of the Compliance Monitoring Staff (now the Office of Compliance Monitoring) estimated that a random sample of disinfectants would reveal a failure rate of up to 20 percent. He concluded that, "This is an unacceptable rate of failure for products with direct public health significance." In a 1983 congressional hearing, the Director of the Office of Pesticide Programs stated that, given the types of failure rates the Beltsville laboratory had found, it was apparent that many batches

of ineffective products had reached the marketplace with the limited level of testing conducted. Furthermore, EPA and state officials, as noted in chapter 2, have stated that the conflicting test results obtained in research on disinfectant efficacy test methods may result as much from ineffective products as from problems with the methods themselves.

Conclusions

EPA lacks assurance that all disinfectants on the market work as claimed. After a disinfectant is registered, its formulation could be altered, intentionally or inadvertently, and ineffective batches introduced into the marketplace. Although EPA has acknowledged this possibility, the agency discontinued its limited testing and enforcement program in 1982. Because state and user monitoring efforts are limited, EPA's decision to stop enforcement testing was, in effect, a decision to let industry regulate the efficacy of marketed disinfectants. However, EPA lacks a formal system to channel complaints about potentially ineffective disinfectants from competitors, users, and others, and to take appropriate enforcement action against ineffective disinfectants. Greater leadership on EPA's part to develop a strategy that pools resources from the states, user groups, industry and others to identify potentially ineffective disinfectants and that specifies the appropriate enforcement action against disinfectants found to be ineffective, would provide better assurance that disinfectants on the market work as claimed. Without such an enforcement strategy, EPA's policy of "let the buyer beware" for disinfectants may be compromising public health and consumer protection. While we recognize that EPA needs to resolve the scientific controversies that surround disinfectant efficacy test methods and performance standards (discussed in ch. 2), these controversies should not prevent EPA from establishing and implementing an enforcement strategy to ensure the efficacy of disinfectants in the marketplace.

Recommendations

We recommend that the Administrator, EPA, develop, publish for comment, and implement an enforcement strategy to ensure that marketed disinfectants work as claimed. This strategy should specify (1) the mechanisms and procedures for identifying potentially ineffective disinfectants; (2) the procedures for investigating and verifying complaints about potentially ineffective disinfectants, including, where necessary, the use of independent laboratory testing; and (3) the criteria and procedures for initiating registration and/or enforcement action against disinfectants found to be ineffective. In light of federal budget constraints, we also recommend that the Administrator explore options for pooling resources from the states, user groups, and industry to implement a

Chapter 4
Limited Monitoring/Enforcement of
Registered Disinfectants

national disinfectant efficacy enforcement strategy. (See ch. 5 for a discussion of options for establishing a laboratory facility to assist in an enforcement program.)

Alternatives for a Disinfectant Laboratory

Many people in industry, the state regulatory laboratories, universities, scientific associations, user groups, and other organizations believe an independent laboratory facility is needed to research and selectively test the efficacy of disinfectants. Some believe that EPA's efforts to resolve the scientific controversies that surround disinfectant efficacy test methods may languish without a federal laboratory facility. EPA officials have objected to such a facility because (1) EPA cannot afford to resume methodology research and testing disinfectants at its limited laboratory facility in Beltsville, Maryland, given its limited budget and competing pesticide program priorities, and (2) they do not think the federal government should test these products. However, fees charged for the privilege of obtaining a disinfectant registration could help offset the costs of a disinfectant laboratory facility. Also, public health may be endangered without such a resource.

This chapter briefly identifies possible alternatives for a laboratory facility, considering (1) the need for and objectives of a laboratory facility, (2) suggested criteria to evaluate alternatives, (3) a list of possible alternatives, and (4) the option of fees. The chapter is not a cost/benefit assessment of various alternatives for a disinfectant laboratory facility. Rather, the purpose of this chapter is to briefly present the pros and cons of the alternatives.

Need for and Objectives of a Disinfectant Laboratory

Previous chapters in this report discussed the need for a laboratory facility to research and test the efficacy of disinfectants. Although their opinions differ, various critics of EPA's regulation of disinfectants from industry, academia, user groups, and other organizations have collectively identified five objectives, listed below, of a disinfectant laboratory facility.

- **Research and development:** the facility should research and develop disinfectant efficacy test methods and performance standards that are accurate and precise, objectively evaluate the validity of registrant-proposed alternative methods and modifications, and actively participate in the scientific exchange of information.
- **Preregistration tests:** the facility should conduct a preregistration-testing program to verify selective disinfectant efficacy claims and ensure the quality and integrity of registrant-submitted data.
- **Laboratory development:** the facility should improve and standardize laboratory procedures, promote good laboratory practices, train laboratory technicians, and conduct a check sample program to improve the

capability of commercial and other laboratories conducting disinfectant efficacy tests.

- Post-registration tests: the facility should conduct a post-registration testing program to verify selective disinfectant efficacy claims in the marketplace and assist in enforcement cases.
- Reference laboratory: the facility should serve as the reference laboratory on questions of test methodology and procedures, referee disputes, and confirm test sample results from state government laboratories.

With respect to the testing functions, the laboratory facility would not need to test every disinfectant product or claim. Proponents of a disinfectant laboratory facility do not support the idea of routine batch-testing to duplicate or replace manufacturers' quality control programs. Rather, the laboratory could focus its efforts on those product claims that are of the greatest significance to public health, such as sporicidal and tuberculocidal claims, randomly check the efficacy of disinfectants in the marketplace, and selectively target those products or chemicals with suspected efficacy problems.

Suggested Criteria for Evaluating Alternatives

Many factors or criteria could be used to evaluate alternatives for meeting the objectives of a disinfectant laboratory facility listed above. However, we suggest four criteria for evaluating alternatives: (1) independence, (2) authority, (3) quality, and (4) cost.

The need for a laboratory facility that is independent has been demonstrated in the scientific controversies surrounding disinfectant efficacy test methods. Market forces and competitive pressures make it difficult to ascertain the validity of scientific disputes. A laboratory facility that provides information to EPA on the validity of disinfectant efficacy test methods and performance standards should be relatively isolated from the profit motive of the industry. The facility should be above reproach to allegations of conflict of interest or the appearance of such conflict.

An independent laboratory facility needs the authority to obtain and test product samples, validate test methods, verify registrants' claims, establish laboratory procedures, and referee disputes.

The laboratory facility and personnel should be of high quality. The laboratory would be unable to restore credibility in disinfectant regulation if its equipment and its personnel were not at the forefront of microbiology and infection control.

Although all of the criteria considered imply cost tradeoffs, the efficiency and practicality of each alternative must be considered. We have not prepared detailed cost estimates for each alternative; rather, we have considered whether the alternatives appear efficient and practical.

Alternatives for a Laboratory Facility

Several alternatives or a combination of alternatives could be developed for operating a laboratory facility to test the efficacy of disinfectants and perform other functions. However, we suggest four alternatives: (1) the federal government, (2) a commercial laboratory, (3) state government(s), and (4) a nonprofit association or foundation.

Many proponents of a disinfectant laboratory facility support the idea of the federal government operating the laboratory, particularly of its resuming disinfectant testing in Beltsville, Maryland. A federally operated facility would satisfy the criterion of independence. EPA, the most likely agency to operate such a lab, has the authority to run it, but is not required to do so under FIFRA. Legislation has been considered in previous congressional sessions to require EPA to establish standards for disinfectants. Quality and cost would be major considerations in establishing a federal laboratory, especially in resuming testing at the Beltsville facility. Both EPA and its critics acknowledge that EPA would need new, highly skilled personnel to operate a testing facility. In addition, EPA's existing facility would need extensive renovation because some of the equipment and supplies at the lab are obsolete and in disrepair.

Cost estimates for establishing a federal disinfectant laboratory range from \$200,000 to \$2 million; annual operating cost estimates range from \$300,000 to \$500,000, depending on the size and scope of operations. Although we were unable to find official historical budget documents from EPA's disinfectant laboratory, various records in the files indicate that EPA may have spent upwards of \$300,000 in fiscal year 1981, the year before the laboratory stopped testing disinfectants. This amount may not cover the costs of a federal laboratory today because of inflation and because a testing program today may be larger in scope and size than the one conducted by the facility in 1981.

Although EPA currently is responsible for registering and enforcing the efficacy of these products, several proponents of a federally operated disinfectant laboratory have suggested that the CDC or the FDA operate the laboratory either alone or in cooperation with EPA. Critics of EPA argue that it lacks personnel with the expertise in infection control practices necessary to effectively regulate disinfectants. They also argue

that the disinfectant program will always be of lower priority than other pesticide programs within EPA and that perhaps it is a program that is misplaced.

Rather than operate its own disinfectant laboratory, EPA could contract for the necessary laboratory services with a commercial facility. This arrangement might offer EPA maximum flexibility in directing the focus of work each year. In addition, since the private sector currently retains the best available scientific and technical personnel and laboratory equipment, EPA might be able to contract for the quality of services needed. However, this alternative might sacrifice independence if the contract laboratory has or has had a close link with the regulated industry. In addition, EPA has been criticized frequently by the Congress for contracting out too many of its responsibilities. (We did not estimate how much it would cost for EPA to contract out for a disinfectant laboratory.)

A third alternative for a disinfectant laboratory is for the states to operate their own laboratories. However, this alternative has already proven unsuccessful. Most states do not operate a disinfectant laboratory today and are unlikely to open labs in the near future because of cost constraints. Further, while the states would be independent, they would lack the necessary authority to test products not sold in their state. Users and consumers would be unfairly disadvantaged if their states were unable to afford a laboratory facility while neighboring states could afford one. In addition, having 50 states research improvements to disinfectant efficacy test methods and test disinfectants would be grossly inefficient.

A fourth alternative could be for a nonprofit association or foundation to operate a disinfectant laboratory. As discussed in chapter 4, the American Dental Association and the National Sanitation Foundation are considering whether and when to establish their own testing programs. While these efforts to help protect public health are commendable, they may not be able to achieve the objectives of a disinfectants laboratory outlined above because they depend on registrants to voluntarily cooperate and submit their products for testing. In addition, these organizations lack authority to take any registration and/or enforcement actions on the basis of their tests.

Fees for a Disinfectant Laboratory

EPA has objected to resuming testing disinfectants at its Beltsville laboratory, in part, because of a lack of resources. However, fees might be one way to help offset the costs of a disinfectant laboratory. Currently, the 1988 amendments to FIFRA (known as FIFRA '88) prohibit EPA from charging such fees. In addition, fees, which industry has opposed, present other obstacles that need to be considered.

EPA's primary pesticide program objective has been to implement FIFRA '88, which involves reviewing the risks and benefits of all pesticides first registered before November 1, 1984—a process known as "reregistration." FIFRA '88 imposes a one-time reregistration fee and an annual maintenance fee to help offset the costs of accelerating reregistration and expediting new registrations. The FIFRA '88 reregistration fees are \$150,000 per active ingredient but are waived for small volume active ingredients (including small volume disinfectant active ingredients) and reduced for small businesses. The annual maintenance fee is designed to provide about \$14 million each year. The FIFRA '88 fees do not explicitly provide funds for operating a disinfectant laboratory. Furthermore, FIFRA '88 prohibits EPA from charging other fees until September 30, 1997, when the FIFRA '88 fee provisions expire. Consequently, the Congress would have to amend FIFRA '88 to allow EPA to charge disinfectant registrants a fee specifically designated for operating a disinfectant laboratory.

The industry has opposed user fees for several reasons but mostly because it views product registrations as a public rather than private benefit. However, charging registrants user fees to finance a disinfectant laboratory, in order for EPA to recover the costs of testing their products, is analogous to charging user fees for EPA to accelerate reregistration of older pesticides and expedite registration of new pesticides. Furthermore, although fees would increase the cost of registering and marketing disinfectants, if registrants want to market disinfectants it seems fair that they finance the cost of demonstrating that their products work as claimed.

Conclusions

Earlier chapters of this report have discussed the need for a laboratory facility to research methods for testing disinfectant efficacy and to test the efficacy of disinfectants. Several alternative ways exist for operating a disinfectant laboratory, but EPA lacks the resources needed to finance such a laboratory. However, fees on disinfectant registrations might be one way to help finance a disinfectant laboratory. Because of the statutory prohibition on new pesticide registration fees and the

unknown effects that disinfectant fees might have on the marketplace, what is needed is a detailed cost/benefit assessment of alternatives for a disinfectant laboratory, including the option of assessing fees to help finance such a facility.

Recommendations

We recommend that the Administrator, EPA, develop a detailed cost/benefit analysis of alternatives for operating a laboratory facility to research and test the efficacy of disinfectants, including the option of charging fees to register disinfectants to help finance such a facility, and submit the results of its analysis to the Congress so that the Congress may weigh the advantages and disadvantages of various alternatives.

Affiliations of Individuals GAO Contacted

Not all individuals GAO contacted officially represented these organizations, but they were employed by or affiliated with these organizations. Some of the individuals contacted from nongovernmental organizations were also employees of disinfectant registrants.

Federal Agencies

Centers for Disease Control
Environmental Protection Agency
Food and Drug Administration

State Governments

California
Florida
Georgia
Illinois
Iowa
Mississippi
New York
North Carolina
Texas
Virginia
Wisconsin

Standard-Setting Organizations

American Society for Testing and Materials
Association of Official Analytical Chemists
National Sanitation Foundation

Professional and Trade Associations

American Dental Association
American Hospital Association
Association for Practitioners in Infection Control
Chemical Specialties Manufacturers Association
Joint Commission on Accreditation of Healthcare Organizations
National Environmental Health Association
National Food Processors Association
National Restaurant Association

Scientific Associations

American Society for Microbiology
Clinical Research Associates

Appendix I
Affiliations of Individuals GAO Contacted

Universities	University of Missouri—Columbia University of North Carolina at Chapel Hill
---------------------	--

Commercial Laboratories	Gibraltar Biological Laboratories, Inc. Hill Top Biolabs, Inc.
--------------------------------	---

Major Contributors to This Report

Resources,
Community, and
Economic
Development Division,
Washington, D.C.

Peter F. Guerrero, Associate Director
J. Kevin Donohue, Assistant Director
William M. Layden, Evaluator-in-Charge
Karen Simpson, Staff Evaluator
Scott W. Weaver, Staff Evaluator
Sarah-Ann Moessbauer, Operations Research Analyst

Office of the General
Counsel, Washington,
D.C.

Doreen Stolzenberg Feldman, Senior Attorney

Glossary

Accuracy	The closeness of an observed result to the true or accepted result.
Antimicrobial Pesticides	With some exceptions, substances and mixtures of substances, intended for inhibiting the growth of, or destroying any bacteria, fungi pathogenic to people and other animals; or viruses declared to be pests and existing in any environment. (For purposes of this report, we have referred to all antimicrobial pesticides for public-health use as "disinfectants.")
Bacteria	Small microorganisms with a relatively primitive cellular organization.
Collaborative Study	A study involving a number of laboratories analyzing the same samples by the same method for the purpose of generating performance data on the method when a competent analyst uses it exactly as written. (Performance data include any values that indicate the reliability, applicability, and practicability that can be expected from the method.)
Disinfectant	As used in this report, any pesticide used on inanimate surfaces or objects and intended to inhibit or destroy bacteria, fungi, or spores causing human disease.
Efficacy	The capacity of a pesticide product when used according to label directions to control the target pest. (As used in this report, the term "efficacy" is synonymous with the terms "product performance" and "effectiveness.")
Fungicide	As defined in this report, a disinfectant intended to destroy fungi.
Fungi	A group of organisms devoid of chlorophyll that cannot manufacture their own food.
Nosocomial Infection	An infection that occurs during or sometimes after hospitalization and was not present or incubating at the time of the patient's admission.

Glossary

Precision	Agreement among repeat observations made under the same conditions.
Reliability	A criterion used to evaluate the validity of a method by measuring the method's ability, when used by qualified analysts, to produce data of a predictable degree of precision and accuracy.
Repeatability	The variability in successive results obtained with the same method on identical test material and under the same conditions (same operator, same apparatus, same laboratory, and same time).
Reproducibility	The variability in individual results obtained with the same method on identical test material but under different conditions (different operator, different apparatus, different laboratory, and/or different time).
Sterilizer/Sporicide	As defined in this report, a disinfectant intended to destroy or eliminate viruses and all living bacteria, fungi, and their spores.
Tuberculocide	An agent that is intended to destroy or inactivate tuberculosis bacteria.
Viricide	An agent that is intended to destroy or inactivate one or more species of virus.
Virus	Any of a group of submicroscopic infective agents that are regarded either as simple microorganisms or as complex molecules. (Viruses are capable of growth and multiplication only in connection with living cells.)
